EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

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

In preparation of the third meeting of competent authorities on tissues and cells on 27-28 May 2009, competent authorities were invited to complete a questionnaire covering the transposition and implementation of Directives 2004/23/EC[1], 2006/17/EC[2] and 2006/86/EC[3] into their national law. This table presents responses regarding the situation from the Member States, Turkey, Norway and Croatia as of December 2008.

1 OJ L 33, 8.2.2003, p. 30

2 OJ L 91, 30.3.2004, p. 25

3 OJ L 256, 1.10.2005, p.32

1. PUBLIC INFORMATION

AUSTRIA	
1.2 Name of the competent authority:	Federal Office for Safety in Health Care (BASG-Bundesamt für Sicherheit im Gesundheitswesen)
1.3 Address	Schnirchgasse 9 A-1030 Vienna
1.4 Telephone (central access point)	+43 (0)50555-36402
1.5 Email (central access point)	Gewebevigilanz@ages.at
1.6 Website	www.basg.at
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	

Others	
BELGIUM	
1.2 Name of the competent authority:	Federal Agency for Medicines and Health Products
1.3 Address	Eurostation II, Place Victor Horta 40/40, 1060 Brussels
1.4 Telephone (central access point)	00 32 (0) 2 524 80 00
1.5 Email (central access point)	info.FAGG_AFMPS@afmps.be
1.6 Website	www.afmps.be
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
BULGARIA	
1.2 Name of the competent authority:	Executive Agency of Transplantation
1.3 Address	Bratia Miladinovi St. 112, Sofia 1202, Bulgaria
1.4 Telephone (central access point)	+3592 8135010/17

1.5 Email (central access point)	iat@bultransplant.bg
1.6 Website	www.bgtransplant.bg
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	
Human organs	Yes
Pharmaceuticals	
Medical devices	
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
CROATIA	
1.2 Name of the competent authority:	Ministry of Health and Social Welfare
1.3 Address	Ksaver 200 a, Zagreb
1.4 Telephone (central access point)	+ 385 1 4607 555
1.5 Email (central access point)	AnteZvonimir.Golem@mzss.hr
1.6 Website	www.mzss.hr
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes

reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	No
Human cells	No
Human reproductive tissues and cells	No
Human blood and blood components	No
Human organs	No
Pharmaceuticals	No
Medical devices	No
Others	No
CYPRUS	
1.2 Name of the competent authority:	Medical and Public Health Services, Ministry of Health Goverment of Cyprus
1.3 Address	YIORKION Bld 1, Prodromou Str & 17, Chilonos Str, 1448, Nicosia Cyprus
1.4 Telephone (central access point)	00357-22605300
1.5 Email (central access point)	an.agrotou@cytanet.com.cy
1.6 Website	www.moh.gov.cy
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	No
Medical devices	No

other	Yes
specify other	Goverment Hospitals
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
CZECH REPUBLIC	
1.2 Name of the competent authority:	Ministry of Health of the Czech Republic
1.3 Address	Palackeho nam. 4, 128 00 Prague, Czech Republic
1.4 Telephone (central access point)	+420 224 972 111
1.5 Email (central access point)	mzcr@mzcr.cz
1.6 Website	www.mzcr.cz
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
other	No
specify other	(till the 18th of October 2008 the responsibility for accreditation; current responsibility for the evidence of the export/import)
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	

1.8 Name of the CA2	State Institute for Drug Control (the competence in the field of human tissues and cells from the 18th October 2008
1.9 Address CA2	Šrobárova 48, 100 41 Praha 10, Czech Republic
1.10 Telephone (central access point) CA2	+420 272 185 111
1.11 Email (central access point) CA2	posta@sukl.cz
1.12 Website CA2	www.sukl.cz
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	Yes
Human blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
Others	Medical devices - partial responsibility
DENMARK	
1.2 Name of the competent authority:	Danish Medicines Agency
1.3 Address	1 Axel Heides Gade, Copenhagen, Denmark.
1.4 Telephone (central access point)	+45 4488 9595
1.5 Email (central access point)	vaevogceller@dkma.dk
1.6 Website	http://www.laegemiddelstyrelsen.dk
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	The National Board of Health
1.9 Address CA2	Islands Brygge 67, 2300 Copenhagen
1.10 Telephone (central access point) CA2	+45 7222 7783
1.11 Email (central access point) CA2	sst@sst.dk

1.12 Website CA2	www.sst.dk
1.13 The Competent authority is responsible for	
Human tissues	No
Human cells	No
Human reproductive tissues and cells	No
Human blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
Others	No
ESTONIA	
1.2 Name of the competent authority:	Estonian State Agency of Medicines
1.3 Address	Nooruse 50411 Tartu Estonia
1.4 Telephone (central access point)	+3727 374140
1.5 Email (central access point)	info@ravimiamet.ee
1.6 Website	www.ravimiamet.ee
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
other	Yes
specify other	Veterinary pharmaceuticals
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	

Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
FINLAND	
1.2 Name of the competent authority:	National Agency for Medicines (NAM)
1.3 Address	Mannerheimintie 103 P.O. Box 55 FI-00301 Helsinki Finland
1.4 Telephone (central access point)	+358-9-4733 41
1.5 Email (central access point)	registry@nam.fi
1.6 Website	www.nam.fi
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
other	Yes
specify other	Advanced therapy medicinal products
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	National Supervisory Authority for Welefare and Health
1.9 Address CA2	P.O. Box 210, FIN-00531 Helsinki
1.10 Telephone (central access point) CA2	+358-9-772 920
1.11 Email (central access point) CA2	kirjaamo@valvira.fi
1.12 Website CA2	www.valvira.fi/en/
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	Yes
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	Authorisations for fertility treatments

FRANCE	
1.2 Name of the competent authority:	1 - Health Ministry 2 - French health products and safety Agency 3 - Agence de la biomédecine
1.3 Address	1 -14 avenue Duquesne -75700-Paris 2 -143/147 bd Anatole France -93285-Saint-Denis-CEDEX 3 - 1 avenue du stade de France -93212- La Plaine -Saint-Denis
1.4 Telephone (central access point)	1- 33 1 01 40 56 50 61 2 -33 1 55 87 40 41 3- 33 1 55 93 65 09
1.5 Email (central access point)	1) genevieve.liffran@sante.gouv.fr 2) Fenzi.teskrat@afssaps.sante.fr 3)francoise.merlet@biomedecine.fr
1.6 Website	http://www.agmed.sante.gouv.fr www.agence-biomedecine.fr http://www.afssaps.sante.fr
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
other	Yes
specify other	ancillary products, cosmetics and tattoo ink, biocides-products, lactarium products, geneticaly modified organisms
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	1 -French health products and safety Agency 2 - Agence de la biomédecine
1.9 Address CA2	1 -143/147 bd Anatole France -93285-Saint-Denis-CEDEX 2 - 1 avenue du stade de France -93212- La Plaine -Saint-Denis
1.10 Telephone (central access point) CA2	1) 33 1 55 87 40 41 and 2) 33 1 55 93 65 09
1.11 Email (central access point) CA2	2) Fenzi.teskrat@afssaps.sante.fr 3) francoise.merlet@biomedecine.fr
1.12 Website CA2	www.agmed.sante.gouv.fr www.agence-biomedecine.fr http://www.afssaps.sante.fr
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	Yes
Human blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes

Others	ancillary products cosmetics and tattoo products biocides, lactarium health products with geneticaly modified organisms
GERMANY	
1.2 Name of the competent authority:	DE
1.3 Address	Paul-Ehrlich-Institut
1.4 Telephone (central access point)	Paul-Ehrlich-Straße 51-59 D-63225 Langen
1.5 Email (central access point)	+49/6103-77-0
1.6 Website	pei@pei.de
1.7 The Competent authority is responsible for	www.pei.de
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	No
other	
specify other	e.g. authorisation of the pharmacies, surveillance of advertisements regarding medicinal products, surveillance of medical devices
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
GREECE	
1.2 Name of the competent authority:	MINISTRY OF HEALTH & WELFARE

1.3 Address	17 Aristotelous, Athens 10187, Greece
1.4 Telephone (central access point)	+30 210-5232-821/9, +30 210-5249-011
1.5 Email (central access point)	no
1.6 Website	www.mohaw.gr
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	HELLENIC TRANSPLANT ORGANIZATION
1.9 Address CA2	5 An. Tsocha, Athens 11521, Greece
1.10 Telephone (central access point) CA2	+30 210 6471200
1.11 Email (central access point) CA2	eom@eom.gr
1.12 Website CA2	www.eom.gr
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	No
Human blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
Others	No
1.14 Name of the competent authority:	National Authority for Medically Assisted Reproduction
1.15 Address:	19 Tritis Septembriou, PO Box 8234, Athens 10010, Greece
1.16 Telephone (central access point):	
1.17 Email (central access point):	iya@iya.gr
1.18 Website:	http://www.iya.gr
1.19 repsonsible for :	Human reproductive tissues and cells
HUNGARY	

1.2 Name of the competent authority:	National Public Health and Medical Officer's Service (NPHMOS) – Office of the Chief Medical Officer
1.3 Address	2-6 Gyáli street, H-1097 Budapest
1.4 Telephone (central access point)	+36 1 476-1100
1.5 Email (central access point)	igazgatas@oth.antsz.hu ;tisztifoorvos@oth.antsz.hu
1.6 Website	www.antsz.hu
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	No
Human organs	No
Pharmaceuticals	Yes
Medical devices	No
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	Yes
Human blood and blood components	No
Human organs	No
Pharmaceuticals	Yes
Medical devices	No
Others	No
IRELAND	
1.2 Name of the competent authority:	Irish Medicines Board
1.3 Address	Kevin O'Malley House Earlsfort Centre, Earlsfort Terrace, Dublin 2. Ireland.
1.4 Telephone (central access point)	00353 1 6764971
1.5 Email (central access point)	imb@imb.ie

1.6 Website	www.imb.ie
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
other	Yes
specify other	Cosmetics, Herbal Medicines
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Not applicable
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
ITALY	
1.2 Name of the competent authority:	Minisetro del lavoro, salute e politiche sociali
1.3 Address	Via Giorgio Ribotta, 5 - 00144 Roma
1.4 Telephone (central access point)	+390659941
1.5 Email (central access point)	i.sturvi@sanita.it
1.6 Website	www.ministerosalute.it
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes

blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	
Medical devices	
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	1) Centro nazionale trapianti (tissues, cells, organs, hsc) 2) Centro nazionale sangue (blood and blood component, cord blood, hsc)
1.9 Address CA2	1)viale Regina Elena, 299 - 00161 Roma 2)Via Giano della Bella , 27 - 00162 Roma
1.10 Telephone (central access point) CA2	1) +39 0649904040 2)+39 0649904953/4954
1.11 Email (central access point) CA2	1) cnt@iss.it 2) cns@iss.it
1.12 Website CA2	1)www.trapianti.ministerosalute.it
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	
Human blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	
Medical devices	
Others	
LITHUANIA	
1.2 Name of the competent authority:	National Transplant Bureau under the Ministry of Health of the Republic of Lithuania
1.3 Address	Santariskiu str. 2, LT-08661, Vilnius, Lithuania
1.4 Telephone (central access point)	+370 5 279 6096
1.5 Email (central access point)	info@transplantacija.lt
1.6 Website	www.transplantacija.lt
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	
blood and blood components	
Human organs	Yes
Pharmaceuticals	
Medical devices	

other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania
1.9 Address CA2	Zalgirio str. 92, LT-09303 Vilnius
1.10 Telephone (central access point) CA2	+370 5 261 5177
1.11 Email (central access point) CA2	vaspvt@vaspvt.gov.lt
1.12 Website CA2	www.vaspvt.gov.lt
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	Yes
Others	Yes
MALTA	
1.2 Name of the competent authority:	Directorate General, Public Health Regulation
1.3 Address	15, Merchants Street, Valletta VLT 2000, Malta
1.4 Telephone (central access point)	(+356) 2299 2426
1.5 Email (central access point)	ray.busuttil@gov.mt
1.6 Website	http://www.sahha.gov.mt/pages.aspx?page=942
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	

1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
NETHERLANDS	
1.2 Name of the competent authority:	Ministry of Health, Welfare and Sport
1.3 Address	P.O. Box 20350 2511 VX The Hague The Netherlands
1.4 Telephone (central access point)	+31 70 340 7911
1.5 Email (central access point)	l.kok@minvws.nl
1.6 Website	www.minvws.nl
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Health Care Inspectorate
1.9 Address CA2	Wilhelmina van Pruisenweg 52 2595 AN The Hague The Netherlands
1.10 Telephone (central access point) CA2	+31 70 304
1.11 Email (central access point) CA2	
1.12 Website CA2	www.igz.nl

1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	Yes
Human blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
Others	
NORWAY	
1.2 Name of the competent authority:	Norwegian Directorate of health
1.3 Address	PO Box 7000, St. Olavs plass 0130 Oslo
1.4 Telephone (central access point)	+ 47 810 200 50
1.5 Email (central access point)	postmottak@helsedir.no
1.6 Website	www.helsedir.no
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	No
Medical devices	Yes
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Norwegian Board og Health is responsible for inspections
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	

Human organs	
Pharmaceuticals	
Medical devices	
Others	
POLAND	
1.2 Name of the competent authority:	National Centre of Tissue and Cell Banking
1.3 Address	Ul. Chałubińskiego 5, 02-004 Warsaw, Poland
1.4 Telephone (central access point)	+48 22 621 75 43, +48 22 696 13 36
1.5 Email (central access point)	akamin@ib.amwaw.edu.pl
1.6 Website	www.kcbtik.pl
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	
blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	CENTRUM ORGANIZACYJNO-KOORDYNACYJNE DO SPRAW TRANSPLANTACJI "POLTRANSPLANT"
1.9 Address CA2	AL. JEROZOLIMSKIE 87, 02-001 WARSAW, POLAND
1.10 Telephone (central access point) CA2	(+48) 22 621 22 40; (+48) 22 621 49 50
1.11 Email (central access point) CA2	
1.12 Website CA2	WWW.POLTRANSPLANT.PL
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	Yes
Pharmaceuticals	
Medical devices	
Others	

PORTUGAL	
1.2 Name of the competent authority:	Autoridade para os Serviços de Sangue e Transplantação (ASST)
1.3 Address	Avenida João Crisóstomo, nº 14 - 4º 1000-179 Lisboa Portugal
1.4 Telephone (central access point)	00 351 213305035
1.5 Email (central access point)	asst@min-saude.pt
1.6 Website	www.asst.min-saude.pt
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	No
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Conselho Nacional Procriação Medicamente Assistida (CNPMA)
1.9 Address CA2	Assembleia da República Palácio de S. Bento 1249-068 Lisboa Portugal
1.10 Telephone (central access point) CA2	00 351 213919303
1.11 Email (central access point) CA2	cnpma.correio@ar.parlamento.pt
1.12 Website CA2	www.cnpma.org.pt (the Website will be available on April 17)
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	Yes
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
ROMANIA	
1.2 Name of the competent authority:	MINISTRY OF PUBLIC HEALTH through NATIONAL TRANSPLANT AGENCY
1.3 Address	2-8 Constantin Caracas Str, Floor 4, Sector 1, 011155, Bucharest
1.4 Telephone (central access point)	+40 317 101473
1.5 Email (central access point)	ant@transplant.ro , ant.msr@gmail.com

1.6 Website	www.transplant.ro
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	MINISTRY OF PUBLIC HEALTH through DEPARTMENT OF CONTROL IN PUBLIC HEALTH
1.9 Address CA2	Cristian Popişteanu no. 1-3, sector 1, Bucharest, 010024
1.10 Telephone (central access point) CA2	+ 4021 3072 557
1.11 Email (central access point) CA2	dcspms@ms.ro
1.12 Website CA2	www.ms.ro
1.13 The Competent authority is responsible for	
Human tissues	No
Human cells	No
Human reproductive tissues and cells	No
Human blood and blood components	No
Human organs	No
Pharmaceuticals	No
Medical devices	No
Others	Yes
SLOVAKIA	
1.2 Name of the competent authority:	Ministerstvo zdravotníctva SR
1.3 Address	Limbová 2 83752 Bratislava
1.4 Telephone (central access point)	+421 2 59373111
1.5 Email (central access point)	office@health.gov.sk
1.6 Website	www.health.gov.sk
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes

reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	Yes
Medical devices	Yes
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
SLOVENIA	
1.2 Name of the competent authority:	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)
1.3 Address	Ptujska ulica 21, SI-1000 Ljubljana
1.4 Telephone (central access point)	+386 8 2000 500
1.5 Email (central access point)	info@jazmp.si
1.6 Website	www.jazmp.si
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes

Medical devices	Yes
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Institute for transplantation of Organs and Tissues of the Republic of Slovenia (Slovenija-transplant)
1.9 Address CA2	Zaloška cesta 7, 1000 Ljubljana
1.10 Telephone (central access point) CA2	+ 386 1 300 68 60
1.11 Email (central access point) CA2	gorazd.cebulc@slovenija-transplant.si
1.12 Website CA2	www.slovenija-transplant.si
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	Yes
Human blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
Others	No
SPAIN	
1.2 Name of the competent authority:	DG Advanced Therapies and Transplantation 28029 Madrid Spain
1.3 Address	C/ Monforte de Lemos 3, Pabellon 3
1.4 Telephone (central access point)	0034918224903
1.5 Email (central access point)	direcciongeneralTAT@msc.es
1.6 Website	www.msc.es
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
other	Yes
specify other	Advanced Therapies

(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Organización Nacional de Trasplantes ONT
1.9 Address CA2	C/ Monforte de Lemos 3, Pabellon 3 28029-Madrid Spain
1.10 Telephone (central access point) CA2	0034918224903
1.11 Email (central access point) CA2	direcciongeneralTAT@msc.es
1.12 Website CA2	www.ont.es
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	No
Human blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
Others	No
SWEDEN	
1.2 Name of the competent authority:	National Board of Health and Welfare
1.3 Address	Socialstyrelsen(National Board of Health and Welfare), SE-106 30 Stockholm
1.4 Telephone (central access point)	National Board of Health and Welfare: +46-(0)75-247 30 00
1.5 Email (central access point)	socialstyrelsen@socialstyrelsen.se
1.6 Website	www.socialstyrelsen.se
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	Yes
blood and blood components	Yes
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
other	No
specify other	Medical Product Agency
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	Medical Product Agency
1.9 Address CA2	L�kemedelsverket(Medical Product Agency), Box 26, SE-751 03 Uppsala

1.10 Telephone (central access point) CA2	+46-(0)18-17 46 00
1.11 Email (central access point) CA2	registrator@mpa.se
1.12 Website CA2	www.lakemedelsverket.se
1.13 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
Human reproductive tissues and cells	No
Human blood and blood components	Yes
Human organs	No
Pharmaceuticals	Yes
Medical devices	Yes
Others	No
TURKEY	
1.2 Name of the competent authority:	Ministry of Health, Turkey Directorate General of Curative Services Unit of Tissue and Cell Transplantation
1.3 Address	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)	+ 90 312 585 15 09 and + 90 312 585 15 10 Mobile Phone of the Head of Unit: + 90 505 914-6065
1.5 Email (central access point)	e- mail of Head of Unit: zeynepcoskun2008@gmail.com
1.6 Website	www.saglik.gov.tr
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	No
blood and blood components	No
Human organs	No
Pharmaceuticals	No
Medical devices	No
other	
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	

1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	
1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	
UNITED KINGDOM	
1.2 Name of the competent authority:	Human Tissue Authority
1.3 Address	Finlaison House 15-17 Furnival Street London WC4A 1AB
1.4 Telephone (central access point)	+44 (0) 20 7211 3400
1.5 Email (central access point)	enquiries@hta.gov.uk
1.6 Website	www.hta.gov.uk
1.7 The Competent authority is responsible for	
Human tissues	Yes
Human cells	Yes
reproductive tissues and cells	No
blood and blood components	No
Human organs	Yes
Pharmaceuticals	No
Medical devices	No
other	No
specify other	
(If applicable) Designated Competent Authority (CA2) (Art. 4(1) Directive2004/23/EC)	
1.8 Name of the CA2	
1.9 Address CA2	
1.10 Telephone (central access point) CA2	
1.11 Email (central access point) CA2	
1.12 Website CA2	

1.13 The Competent authority is responsible for	
Human tissues	
Human cells	
Human reproductive tissues and cells	
Human blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Others	

2. ORGANISATIONAL STRUCTURE AND COMPETENCE

AUSTRIA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The AGES PharmMed (Agency for food and health safety) is an agency of the ministry of Health. It contains the Federal Office for Safety in Health Care (BASG-Bundesamt für Sicherheit im Gesundheitswesen)
BELGIUM	
2.1 Short description of the legal status and organisation of the competent authority (ies)	Agency under the authority of the Minister of Health
BULGARIA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The Executive Agency of Transplantation is second level administrator with budget credits at the Ministry of Health of Republic of Bulgaria and according to Organ, tissue and cell transplantation act Art.11, par.4 it is the Competent Authority for tissues and cells.
CROATIA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	Ministry of Health and Social Welfare is competent authority for tissue and cells - Department for Health Inspection is technical units performing inspection and supervision of the blood and TE establishments -Department for inspection and blood, tissue and cells monitoring is technical units responsible for the licensing procedure of blood and TE.
CYPRUS	
2.1 Short description of the legal status and organisation of the competent authority (ies)	Department of Ministry of Health
CZECH REPUBLIC	
2.1 Short description of the legal status and organisation of the competent authority (ies)	State Institute for Drug Control is the independent authority with the competence stated by respective Acts (on pharmaceuticals, on tissues and cells for human application, on medical devices). The director of this institute is nominated by the minister of health.
DENMARK	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The Ministry of 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 the National Board of Health. The former has direct responsibility for the inspection of the tissue establishments, the implementation of the transposed Regulations and its Executive Orders. The National

	Board of Health has responsibility for defining and advising on the national regulations, transposed from the Tissue Establishment Directives, related to donation, procurement and testing for infectious markers.
ESTONIA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	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 and processing of human cells, tissues and organs. Agency consists of seven departments. Department of biologicals is responsible for supervision of blood and blood componenst and processing of human cells, tissues and organs.
FINLAND	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The National Agency for Medicines (NAM) 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 and medical devices on the market in Finland. NAM supervises also the safety and quality of blood products and human tissues/cells intented for human applications.
FRANCE	
2.1 Short description of the legal status and organisation of the competent authority (ies)	1) Health Ministry : it prepares all the legal framework of the activities on ethical and medical aspects of tissus and cells. 2) French Health and Safety Agency :it is responsible of the evaluation and the control of health products(for more information: http://www.afssaps.fr) 3) Agence de la biomédecine It combines the four fields of organ procurement, assisted reproduction, human embryology and genetics. Its close links with medical teams and patients facilitates the respect for safety and quality, anticipation, ethics and transparency. Given its expertise in these fields, the Agence de la biomédecine is the CA for all medical, scientific and ethical aspects relating to these issues. However, it should be stressed that in the vigilance field, Afssaps (French Health products and safety agency) is the competent authority for biovigilance and materio vigilance in relation with the Agence de la biomédecine whereas the Agence de la biomédecine is the CA for ART vigilance
GERMANY	

2.1 Short description of the legal status and organisation of the competent authority (ies)	- state competent authorities of the german Laender (responsible for the authorisation of the collection, the establishments, the authorisation of the manufacturing/processing procedures, import and the post marketing surveillance) - Paul-Ehrlich-Institut, federal competent authority (responsible for the authorization of functional tissue preparations as medicinal products, the recognition of tissue preparation authorizations provided by other EU member state competent authorities, tissue vigilance)
GREECE	
2.1 Short description of the legal status and organisation of the competent authority (ies)	Hellenic Transplant Organization Independent authority under supervision of Health Ministry with the general competence in transplantation matters in Greece
HUNGARY	
2.1 Short description of the legal status and organisation of the competent authority (ies)	NPHMOS is an independent authority under the direction of the Ministry of Health, responsible for the management, coordination and control of public health, epidemiology, health development (protection and maintenance of health, health education) and health administration activities, as well as the supervision (licensing and control) of healthcare. The operation of the National Public Health and Medical Officer Service is regulated by the Act XI of year 1991. NPHMOS is directed by the Chief Medical Officer who fulfils his tasks under the direct supervision of the Minister of Health. The central organization of the National Public Health and Medical Officer Service is the Office of the Chief Medical Officer. There are 9 national centres dealing with research and methodology, they participate in the fulfilment of tasks. The Office fulfils tasks via its regional and small regional institutions
IRELAND	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The Irish Medicines Board is an independent agency which reports to the Department of Health and Children.
ITALY	
2.1 Short description of the legal status and organisation of the competent authority (ies)	1) CNT The National Transplant Centre is located within the Istituto Superiore di Sanità and it's a technical institute of the Ministry of Health. 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) 2)CNS The National Blood Centre has been instituted by the Ministry of Health at the National Institute of Health (Istituto Superiore di sanità) in order to perform the coordination and technical and scientific control of all transfusion medicine issues ruled by national laws and European provisions, including plasma products, plasma pharmaceutical industries, and the coordination of the Italian Cord Blood Banks Network
LITHUANIA	

2.1 Short description of the legal status and organisation of the competent authority (ies)	1-2. National Transplant Bureau and Accreditation Agency are State Care Agencies under the Ministry of Health. 3. The Ministry of Health of the Republic of Lithuania is also a CA, responsible for Human reproductive tissues and cells. 4. State Medical Audit Inspectorate under the Ministry of Health of the Republic of Lithuania is also a CA, which performs audit in the case of deficiencies. It controls over and assesses the quality of health care institution's (including TE) cervices
MALTA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The Competent Authority is the Directorate General for Public Health Regulation within the Ministry for Social Policy. Currently, the Director General of Public Health Regulation performs the duties of Chief Government Medical Officer and Superintendent of Public Health in terms of law. The Superintendent of Public Health is the Licensing Authority for the purposes of the Human Blood and Transplant Act (Cap.483) http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_15/Chapt483.pdf
NETHERLANDS	
2.1 Short description of the legal status and organisation of the competent authority (ies)	Officially the Minister of Health, Welfare and Sport is responsible. Depending on the topic the Health Care Inspectorate (IGZ) or the Ministry of Health (VWS) is responsible
NORWAY	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The Norwegian directorate of Helath is a directorate under Ministry of Helath
POLAND	
2.1 Short description of the legal status and organisation of the competent authority (ies)	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.
PORTUGAL	
2.1 Short description of the legal status and organisation of the competent authority (ies)	National Council for Assisted Reproduction Technologies (CNPMA) is an independent authority that functions under the aegis of the Portuguese Assembly of the Republic, with powers, in general, to pronounce on ethical, social and legal questions of assisted reproduction technologies. Autoridade para os Serviços de Sangue e Transplantação has regulatory functions in the quality and safety of tissues and cells, as well as inspection and authorisation of tissue establishment, organisations responsible for human application and procurement organisations.
ROMANIA	

2.1 Short description of the legal status and organisation of the competent authority (ies)	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. Department of Control in Public Health is the actual name of the ex State Sanitary Inspection -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.
SLOVAKIA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	Department of Health of the Ministry of Health
SLOVENIA	
2.1 Short description of the legal status and organisation of the competent authority (ies)	JAZMP is Public Agency and is competent authority for medicinal products for human and veterinary use, medical devices, blood and tissues/cells. Regard to field of tissues and cells JAZMP is competent for Authorization and Inspection of Tissue Establishments. Slovenija transplant is responsible for coordination expert units in donor hospitals, which cooperate in deceased donors, procurement of organs, transplantation of organs and storing, but also HLA typing of tissues and selection donors and recipients. Regard to field of tissues and cells Slovenija transplant is competent for tissues and cells Registry, Traceability, Transparency and Histovigilance. For reproductive cells also The National Board for biomedically assisted procreation at Ministry of Health has some responsibilities according Infertility treatment and procedures of biomedically-assisted procreation .
SPAIN	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The ONT is a department which is integrated in the DG of Advanced Therapies and Transplantation
SWEDEN	
2.1 Short description of the legal status and organisation of the competent authority (ies)	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 tissues and cells for use in the manufacture of medicinal products.
TURKEY	

2.1 Short description of the legal status and organisation of the competent authority (ies)	Directorate General of Curative Services Unit of Tissue and Cell Transplantation
UNITED KINGDOM	
2.1 Short description of the legal status and organisation of the competent authority (ies)	The HTA was established on 1 April 2005 under the Human Tissue Act 2004 (HT Act) to regulate the removal storage use and disposal of human bodies, organs and tissues for a number of purposes e.g transplantation, research, education and training. The HTA is one of the Competent Authorities in the UK under the European Union Tissues and Cells Directives (2004/23/EC, 2006/17/EC and 2006/86/EC). As a result of the transposition of the EUTCD into UK law through the Human Tissue (Quality and Safety for Human Application) Regulations 2007 the HTA has a legal obligation to ensure that all establishments carrying out activities relating to all tissues and cells intended for human application (other than reproductive cells) are licensed and meet all the requirements under relevant legislation. The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health.

3. TRANSPOSITION

AUSTRIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Gewebesicherheitsgesetz - GSG, BGBl. I Nr. 49/2008
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Gewebeentnahmeverordnung GEEVO, BGBl. II Nr. 191/2008
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Gewebebankenverordnung – GBVO, BGBl. II Nr. 192/2008 Gewebevigilanzverordnung – GVVO, BGBl. II Nr. 190/2008
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
BELGIUM	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Wet van 19 DECEMBER 2008 inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek Loi du 19 DECEMBRE 2008 relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique published in the BELGISCH STAATSBLAD — MONITEUR BELGE (pages 68774 - 68787) of 30.12.2008.
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	no
Name of the implementing measure	
Expected transposition of the directive 2006/17/EC	2009
3.1 Has Directive 2006/86/EC been transposed into national law?	no
Name of the implementing measure	
Expected transposition of the directive 2006/86/EC	2009
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	

BULGARIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Paragraph 1a from Supplementary Provisions of Organ, tissue and cell transplantation act.
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Art.4, para 1, para 6, para 7 from Organ, tissue and cell transplantation act (Ordinance N: 6/5.3.2007, Ordinance N:7/5.3.2007).
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Art.4, para 1, Art.11, para 5, p.7, 12, 13, 14, 15 and 16 from Organ, tissue and cell transplantation act (Ordinance N: 6/5.3.2007, Ordinance N:7/5.3.2007, Ordinance N:10/30.3.2007, Ordinance N:22/3.5.2007, Ordinance N:21/3.5.2007).
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
CROATIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	• The "Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes (OG n177/04) • Ordinance – Measures to assure the safety and quality of parts of the human body for medical use – 2699.25 Nov 2005. • Ordinance – Method of filing medical documents on performed explantations and transplantations of parts of the human body – (2956) 16 Dec 2005. • Ordinance – Storage and transportation of parts of the human body intended for transplantation – (2955) 16 Dec 2005. • Ordinance – Work and supervision of health establishments or parts thereof with tissue banks – (6) 20 Dec 2005. • Ordinance on the reporting procedure of the death of person eligible as donors of parts of the human body for therapeutically oriented transplantation. • Act amending the Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes (adopted on Aprile 3th 2009)
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	• The "Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes (OG n177/04) • Ordinance – Measures to assure the safety and quality of parts of the human body for medical use – 2699.25 Nov 2005. • Ordinance – Method of filing medical documents on performed explantations and transplantations of parts of the human body – (2956) 16 Dec 2005. • Ordinance – Storage and

	transportation of parts of the human body intended for transplantation – (2955) 16 Dec 2005.
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	• The "Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes (OG n177/04) • Ordinance – Measures to assure the safety and quality of parts of the human body for medical use – 2699.25 Nov 2005. . • Ordinance – Method of filing medical documents on performed explantations and transplantations of parts of the human body – (2956) 16 Dec 2005. • Ordinance – Storage and transportation of parts of the human body intended for transplantation – (2955) 16 Dec 2005. • Ordinance – Work and supervision of health establishments or parts thereof with tissue banks – (6) 20 Dec 2005. • Ordinance – Criteria for the allocation of parts of the human body and the method of keeping the national waiting list- (2954) 15 Dec 2005. • Act amending the Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes (adopted on Aprile 3th 2009)
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
CYPRUS	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Law 187(1)/2007
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Law 187(1)/2007
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Regulations of Law 187(1)/2007 according to Article 54
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
CZECH REPUBLIC	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes

Name of the implementing measure	Act no. 296/2008 Coll. on ensuring quality and safety of human tissues and cells intended for human application and on amendment of related acts Decree no. 422/2008 Coll. on further requirements for ensuring quality and safety of human tissues and cells intended for human application
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Act no. 296/2008 Coll. on ensuring quality and safety of human tissues and cells intended for human application and on amendment of related acts Decree no. 422/2008 Coll. on further requirements for ensuring quality and safety of human tissues and cells intended for human application
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Act no. 296/2008 Coll. on ensuring quality and safety of human tissues and cells intended for human application and on amendment of related acts Decree no. 422/2008 Coll. on further requirements for ensuring quality and safety of human tissues and cells intended for human application
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	a) It would be better, if the mother directive and the technical directives appear in short time interval (better understanding, easier transposition). Further difficulty is the delay of regulation promised by directives (e.g. European coding system). b) No system for individual questions of CA concerning explanation/use of some provisions of directives (to be sure, that the answer will be received). See also item 15.1., 15.4.
DENMARK	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Vævsloven, nr. 273 af 1. april 2006, som ændret ved lov nr. 534 af 17. juni 2008 (The Tissue Law).
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Executive orders: 'Bekendtgørelse 879 af 18. august 2006'as updated by 'Bekendtgørelse 984 af 2. august 2007'. Bekendtgørelse 753 af 3. juli 2006
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes

Name of the implementing measure	Executive order: 'Bekendtgørelse nr. 289 af 26. marts 2007' as updated by 'Bekendtgørelse nr. 1266 af 15. december 2008'.

Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	- coordinating the implementation of the transpositions when regulations were not finalised.
ESTONIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Law of processing and transplantation of cells, tissues and organs Rakkude, kudede ja elundite käitlemise ja siirdamise seadus1 https://www.riigiteataja.ee/ert/act.jsp?id=12980151 Law of artificial fertilization and embryo protection Kunstliku viljastamise ja embrüokaitse seadus https://www.riigiteataja.ee/ert/act.jsp?id=13097625
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Regulation on donor selection criteria, list of laboratory test for donors and rules and conditions for providing tests Rakkude, kudede ja elundite doonorite valiku kriteeriumid ja doonoritele ettenähtud kohustuslike laboratoorsete uuringute loetelu ning uuringute tegemise tingimused ja kord https://www.riigiteataja.ee/ert/act.jsp?id=13097330 Regulation on processing cells tissues and organs Rakkude, kudede ja elundite käitlemise eeskiri* https://www.riigiteataja.ee/ert/act.jsp?id=13097340
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Regulation on biovigilance and recall of cells, tissues and organs, information forms of serious adverse reactions and serious adverse events Rakkude, kudede ja elundite suhtes kohaldatava biovalvsuse ja tagasikutsumise tingimused ja kord ning raskest kõrvalekaldest ja raskest kõrvaltoimest teatamise vormid https://www.riigiteataja.ee/ert/act.jsp?id=13097311 Regulation on processing cells tissues and organs Rakkude, kudede ja elundite käitlemise eeskiri* Regulation on documents and data for application of processing of cells, tissues and organs Rakkude, kudede ja elundite käitlemise tegevusloa taotlemisel esitatavate dokumentide ja andmete loetelu https://www.riigiteataja.ee/ert/act.jsp?id=13097300
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	Estonia does not have system of independent tissue establishments. Preparation processes have historically been a part of transplantation. Separation of preparation processes to tissue establishments has formed subunits (tissue establishments) at the department levels of hospitals. Procurement process is partly under supervision of

	Healthcare Board.
FINLAND	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Act on the Medical Use of Human Organs, Tissues and Cells (101/2001; revised 547/2007); into force 1st June 2007
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Administrative Regulation 3/2007, given ny NAM; into force 28th December 2007
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Decree 1302/2007 given by the Ministry of Social Affairs and Health; into force 28th December 2007 And Administrative Regulation 3/2007, given ny NAM; into force 28th December 2007
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
FRANCE	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Regulation for activities and products about tissues and cells (excluding gamets and embryo) : - Ordonnance n° 2007-613 du 26 avril 2007 - Décret n° 2008-968 du 16 septembre 2008 (autorisations d'activités et de produits) - Décret n° 2008-891 du 2 septembre 2008 (importation et exportation) - Arrêté du 28 octobre 2008 (dossier d'autorisation import/export) 2) Regulation for gamets and embryo Ordonnance n°2008-480 du 22 mai 2008 transposant en matière de don de gamètes et d'assistance médicale à la procréation la directive 2004/23/CE
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	1) For tissues and cells (excluding gamets and embryo) : - Décret n 2005-1618 du 21 décembre 2005 (règles de sécurité sanitaire) Arrêté du 21 décembre 2005 (modalités d'application des régles de sécurité sanitaire) - Arrêté du 1er avril 1997 r(ègles de bonnes pratiques de prélèvement des tissus) - Arrêté du 16 décembre 1998 (règles de bonnes pratiques de prélèvement, transport, transformation des cellules souches hématopoiétiques et des cellules mononuclées sanguines) 2) for gamets and embryo Décret n° 2008-588 du 19 juin 2008 transposant en matière de don de gamètes et

	d'assistance médicale à la procréation la directive 2004/23/CE du Parlement européen et du Conseil du 31 mars 2004
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	- Arrêté du 29 décembre 1998 (bonnes pratiques conservation, transformation et transport des tissus) - Décret n° 2008-968 du 16 septembre 2008 (autorisation activités et produits) Décret n° 2003-1206 du 12 décembre 2003 (biovigilance) Décret no 2008-588 du 19 juin 2008 (gamètes et ART) Arrêté du 18 décembre 2008 fixant les éléments d'information relatifs au signalement d'un incident ou d'un effet indésirable dans le cadre du dispositif de vigilance relatif à l'assistance médicale à la procréation
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	In ART sector, there are several difficulties including the following requirements: -an European coding for non partner reproductive cells and embryos donation -air quality in the laboratory - the screening for HIV and hepatitis infections at donation even in partner donation : -processes in ART - Inspections of the 300 ART centre every two years because of an insufficient number of inspectors. These requirements are inapplicable in the reproductive sector. Moreover they don't make sense as it was fully said by ESHRE and EACC, the professional societies in reproduction and embryology. For these reasons, it was impossible to transpose these requirements in the french regulations
GERMANY	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	AMG (German Medicinal Products Act), AMWHV, TPG, TPG-GewV
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	see above 3.1
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	see above 3.1
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes

specify difficulties	There were national discussions regarding the specific legal framework chosen for the transposition.
GREECE	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Presidential Decree (P.D.) 26/2008, published in A51/2008 Government Paper
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Presidential Decree (P.D.) 26/2008, published in A51/2008 Government Paper
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Presidential Decree (P.D.) 26/2008, published in A51/2008 Government Paper
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
HUNGARY	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Act CLIV. of year 1997. on health care Act XLVII. of year 1997. on protection of personal health data Act of IV. of year 1978. on penalty law Ministerial Decree 30/1998 – on human reproductive processes Ministerial decree 18/1998 on tissue and cell establishments Ministerial decree 2/2004 on vocational codes of health services and on register of health care services Ministerial decree 60/2003 on minimum requirements of health care services Governmental decree 96/2003 the licensing procedure of health care services
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Act CLIV. of year 1997. on health care Act XLVII. of year 1997. on protection of personal health data Act of IV. of year 1978. on penalty law Ministerial Decree 30/1998 – on human reproductive processes Ministerial decree 18/1998 on tissue and cell establishments Ministerial decree 2/2004 on vocational codes of health services and on register of health care services Ministerial decree 60/2003 on minimum requirements of health care services Governmental decree 96/2003 the licensing procedure of health care services
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes

Name of the implementing measure	Act CLIV. of year 1997. on health care Act XLVII. of year 1997. on protection of personal health data Act of IV. of year 1978. on penalty law Ministerial Decree 30/1998 – on human reproductive processes Ministerial decree 18/1998 on tissue and cell establishments Ministerial decree 2/2004 on vocational codes of health services and on register of health care services Ministerial decree 60/2003 on minimum requirements of health care services Governmental decree 96/2003 the licensing procedure of health care services
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
IRELAND	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Statutory Instrument No. 158 of 2006 European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Statutory Instrument No. 158 of 2006 European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Statutory Instrument No. 598 of 2007 European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007.
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
ITALY	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	decreto legislativo 6 novembre 2007, n 191
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	no
Name of the implementing measure	
Expected transposition of the directive 2006/17/EC	end of 2009
3.1 Has Directive 2006/86/EC been transposed into national law?	no
Name of the implementing measure	

Expected transposition of the directive 2006/86/EC	end of 2009
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
LITHUANIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	1) Lietuvos Respublikos žmogaus audinių, ląstelių ir organų donorystės ir transplantacijos įstatymas (tekstas) (Žin., 1996, Nr. 116-2696; 2006, Nr. 119-45454) **(LAW ON DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS**, by the order of the Minister of Health of the Republic of Lithuania on 19 November 1996 No I-1626 (As last amended on 19 October 2006 - No X-867) http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=230615 http://www.transplantacija.lt/content/teisesaktai.en.html 2) Mirusio žmogaus audinių ir ląstelių, gyvo Žmogaus audinių ir ląstelių donorystės, įsigijimo, ištyrimo, kodavimo, apdorojimo, konservavimo, laikymo, paskirstymo sąlygų tvarkos aprašas **(DESCRIPTION OF RULES ON DONATION, PROCUREMENT, TESTING, CODING, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION OF HUMAN TISSUES AND CELLS FROM DECEASED AND LIVING DONORS,** by the order of the Minister of Health of the Republic of Lithuania on 21 May 2007 No V-397 (As last amended on 7 December 2007 – No V-1010) http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=311233 http://www.transplantacija.lt/content/teisesaktai/aktai/samisakymai.lt.html 3) 2008 m. rugsėjo 5 d. įsakymas Nr. V-857 "Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2004 m. gegužės 14 d. įsakymo Nr. V-364 „Dėl licencijuojamų asmens sveikatos priežiūros paslaugų sąrašų patvirtinimo“ papildymo“ (Žin., 2008, Nr. 106-4053; 2004, Nr. 86-3152) – **CONCERNING THE LIST OF LICENSING OF PERSON HEALTH CARE CERVICES** (ABOUT LICENSING OF TISSUE ESTABLISHMENTS), the order of the Minister of Health of the Republic of Lithuania on 5 September 2008 No V-857 http://www.transplantacija.lt/content/teisesaktai/aktai/samisakymai.lt.html 4) 2009 m. kovo 13 d. įsakymas Nr. V-188 “Dėl specialiųjų reikalavimų personalui, teikiančiam audinių ir (ar) ląstelių įsigijimo (paėmimo), apdorojimo, konservavimo, laikymo, paskirstymo paslaugas, ir įrangai, reikalingai audiniams ir (ar) ląstelėms įsigyti (paimti), apdoroti, konservuoti, laikyti, paskirstyti, aprašų patvirtinimo” (Žin., 2009, Nr. 35-1364) - **ABOUT SPECIFIC REQUIREMENTS FOR PERSONEL WHO PERFORMS HUMAN TISSUES AND CELLS PROCUREMENT, PROCESSING, PRESERVATION,**

	STORAGE AND DISTRIBUTION, AND REQUIREMENTS FOR EQUIPMENT NEEDED FOR HUMAN TISSUES AND CELLS PROCUREMENT, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION, the order of the Minister of Health of the Republic of Lithuania on 13 March 2009 No V-188 http://www.transplantacija.lt/content/teisesaktai/aktai/samisakymai.lt.html http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_bin?p_id=340160 http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=340160&p_query=&p_tr2=
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	Yes, partly
Name of the implementing measure	There is transposed Directive's Article 1 c),d),e),f), g); Article 2; Article 3a) ; Article 4 part 1 a) and b); Annex I; II; IV into: Mirusio žmogaus audinių ir ląstelių, gyvo Žmogaus audinių ir ląstelių donorystės, įsigijimo, ištyrimo, kodavimo, apdorojimo, konservavimo, laikymo, paskirstymo sąlygų tvarkos aprašas **(DESCRIPTION OF RULES ON DONATION, PROCUREMENT, TESTING, CODING, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION OF HUMAN TISSUES AND CELLS FROM DECEASED AND LIVING DONORS,** by the order of the Minister of Health of the Republic of Lithuania on 21 May 2007 No V-397(As last amended on 7 December 2007 - No V-1010) http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=311233 http://www.transplantacija.lt/content/teisesaktai/aktai/samisakymai.lt.html
Expected transposition of the directive 2006/17/EC	It is not transposed Directive's Article 1a),b), Article 3b); Article's 4 part 2; Annex III If no, when is transposition approximately expected? (dd/mm/yyyy) : **not specified** (probably, when Parliament makes decision on the (use of reproductive cells?)

	regulation of donation of reproductive cells
3.1 Has Directive 2006/86/EC been transposed into national law?	yes partly,
Name of the implementing measure	It is transposed Art 1; Art 2 (exept a) and b)); Art 3, Art 4; Art 5; Art 6 (exept part 2); Art 7, Art 8, Art 9, Art 10 into: 2007 m. gegužės 22 d. įsakymas Nr. V-401 "Dėl pranešimų apie nepageidaujamas reakcijas ir (ar) reiškinius, susijusius su audinių ir ląstelių įsigijimu, ištyrimu, apdorojimu, laikymu, paskirstymu ir transplantacija, tvarkos aprašo patvirtinimo" (Žin., 2007, Nr.58-2253) - **DESCRIPTION OF THE RULES REGARDING NOTIFICATION OF SERIOUS ADVERSE REACTIONS AND EVENTS RELATED TO DONATION, PROCUREMENT, TESTING, PROCESSING, PRESERVATION, STORAGE, DISTRIBUTION AND TRANSPLANTATION OF HUMAN TISSUES AND CELLS,** by the Order of the Minister of Health of the Republic of Lithuania on 22 May 2007 No V-401 http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_bin?p_id=298220 http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=298220&p_query=&p_tr2= http://www.transplantacija.lt/content/teisesaktai/aktai/samisakymai.lt.html
Expected transposition of the directive 2006/86/EC	It is not transposed Art 2 a) and b); Art 6 part 2 (about gametes) Transpostion of following parts is not specified (actually, when Parliament makes decision on the use of reproductive cells).
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	The shortage of tissue and cell specialists and lack of competent lawyers in this field had been recognized as the main difficulties of transposition. No consensus in the Parliament of Lithuania on the use of reproductive cells had been recognized as main reason for the delay.
MALTA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	The Tissues and Cells (Quality and Safety) Regulations (LN271/06) http://www.doi.gov.mt/EN/legalnotices/2006/11/LN271.pdf
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	The Tissues and Cells (Quality and Safety) Regulations (LN271/06) http://www.doi.gov.mt/EN/legalnotices/2006/11/LN271.pdf

Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	The Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations (L.N337/07) http://www.doi.gov.mt/EN/legalnotices/2007/10/LN%20337.pdf
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
NETHERLANDS	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Wet veiligheid en kwaliteit lichaamsmateriaal (Act on human tissues and cells) and lower regulation Eisenbesluit lichaamsmateriaal 2006, published in Staatsblad 2007, 58 and 59
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Eisenbesluit lichaamsmateriaal 2006, Staatscourant 2007, nr. 63, p.18.
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Eisenbesluit lichaamsmateriaal 2006, Staatscourant 2007, nr. 63, p.18.
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
NORWAY	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Forskrift 7. mars 2008 om krev til kvalitet og sikkerhet ved håndtering av humane celler og vev
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Forskrift 7. mars 2008 om krav til kvalitet og sikkerhet ved håndtering av humane celler og vev
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Forskrift 7. mars 2008 om krav til kvalitet og sikkerhet ved håndtering av humane celler og vev

Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
POLAND	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów(Dz. U. 2005, Nr 169, poz. 1411) Zarządzenie Ministra Zdrowia w sprawie nadania statutu Krajowemu Centrum Bankowania Tkanek i Komórek (Dz.Urz.MZ.06.01.02)
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów(Dz.U.05.169.1411) Rozporządzenie Ministra Zdrowia z dnia 1 grudnia 2006 r. w sprawie sposobu prowadzenia centralnego rejestru sprzeciwów oraz sposobu ustalania istnienia wpisu w tym rejestrze (Dz.U.06.228.11350) Rozporządzenie Ministra Sprawiedliwości z dnia 30 października 2007 r. w sprawie sposobu i trybu uzyskania informacji od prokuratora lub stanowiska sądu rodzinnego o niewyrażeniu sprzeciwu na pobranie ze zwłok komórek, tkanek i narządów (Dz.U.07. 210.1532) Rozporządzenie Ministra Zdrowia z dnia 16 lipca 2007 r. w sprawie szczegółowych warunków pobierania, przechowywania i przeszczepiania komórek, tkanek i narządów (Dz.U.07.138.973) Rozporządzenie Ministra Zdrowia z dnia 9 października 2008 r. w sprawie wymagań, jakie powinien spełniać system zapewnienia jakości w bankach tkanek i komórek (Dz.U.08.190.1169)
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów (Dz.U.05.169.1411) Rozporządzenie Ministra Zdrowia z dnia 16 lipca 2007 r. w sprawie szczegółowych warunków pobierania, przechowywania i przeszczepiania komórek, tkanek i narządów (Dz.U.07.138.973) Rozporządzenie Ministra Zdrowia z dnia 9 października 2008 r. w sprawie wymagań, jakie powinien spełniać system zapewnienia jakości w bankach tkanek i komórek (Dz.U.08.190.1169) Rozporządzenie Ministra Zdrowia z dnia 20 listopada 2006 r. w sprawie wymagań fachowych i sanitarnych dla banków tkanek i komórek (Dz.U.06.218.1598) Rozporządzenie Ministra Zdrowia z dnia 13 grudnia 2006 r. w sprawie trybu przeprowadzania kontroli w podmiotach wykonujących czynności związane z pobieraniem, przechowywaniem i przeszczepianiem komórek, tkanek i narządów (Dz.U.06.237.1722)

Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	There are no regulations concerning reproductive cells. Prime Minister nominated a working group to create regulations regarding reproductive cells
PORTUGAL	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Law nº 12/2009 Diário da República, 1ª série - Nº 60 de 26 de Março de 2009 Estabelece o regime jurídico da qualidade e segurança relativa à dádiva, colheita, análise, processamento, preservação, armazenamento, distribuição e aplicação de tecidos e células de origem humana, transpondo para a ordem jurídica interna as Directivas nºs 2004/23/CE, do Parlamento Europeu e do Conselho, de 31 de Março, 2006/17/CE, da Comissão, de 8 de Fevereiro, e 2006/86/CE, da Comissão, de 24 de Outubro.
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Law nº 12/2009 Diário da República, 1ª série - Nº 60 de 26 de Março de 2009 Estabelece o regime jurídico da qualidade e segurança relativa à dádiva, colheita, análise, processamento, preservação, armazenamento, distribuição e aplicação de tecidos e células de origem humana, transpondo para a ordem jurídica interna as Directivas nºs 2004/23/CE, do Parlamento Europeu e do Conselho, de 31 de Março, 2006/17/CE, da Comissão, de 8 de Fevereiro, e 2006/86/CE, da Comissão, de 24 de Outubro
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Law nº 12/2009 Diário da República, 1ª série - Nº 60 de 26 de Março de 2009 Estabelece o regime jurídico da qualidade e segurança relativa à dádiva, colheita, análise, processamento, preservação, armazenamento, distribuição e aplicação de tecidos e células de origem humana, transpondo para a ordem jurídica interna as Directivas nºs 2004/23/CE, do Parlamento Europeu e do Conselho, de 31 de Março, 2006/17/CE, da Comissão, de 8 de Fevereiro, e 2006/86/CE, da Comissão, de 24 de Outubro
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	The Law was published on March 26, 2009. The implementation process is just starting. Several problems are anticipated for the ART centres.
ROMANIA	

3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Law no. 588/2004, Law no. 95/2006 concerning the reform in the public health - TITLE VI, Minister's of Public Health Order no. 1290/2006, Minister's of Public Health Order no. 1077/2006, Minister's of Public Health Order no. 1242/2007, Minister's of Public Health Order no. 1194/2007
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Minister's of Public Health Order no. 1242/2007, Minister's of Public Health Order no. 1763/2007
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Minister's of Public Health Order no. 1242/2007, Minister's of Public Health Order no. 1763/2007
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
SLOVAKIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Law 282/2006 of June 1, 2007, Governmental Decree 324/2006
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Governmental Decree 20/2007 of January 15, 2007
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Governmental Decree 622/2007 of December 12, 2007
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	The issues of coding could not be transposed, because the final decision of coding has not been taken so far
SLOVENIA	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	§ Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) and § Rules on conditions and procedure for import and export and entry and carry out of human tissues and cells (OG RS, No. 70/2008)
Expected transposition of the directive 2004/23/EC	

3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	§ Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) § Rules on donating and production of human tissues and cells (OG RS, No. 70/2008)
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	§ Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) § Rules on traceability of human tissues and cells and products and materials, which are coming in contact with tissues and cells (OG RS, No. 70/2008) § Rules on histovigilance (OG RS, No. 70/2008) § Rules on adopting, processing, storing, releasing and distributing human tissues and of cells (OG RS, No. 70/2008) § Rules on conditions for granting permission for performing of activity of supply with human tissues and cells (OG RS, No. 70/2008)
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
SPAIN	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Real Decreto 1301/2006 de 10 de noviembre, por el que se establecen las normas de calidad y seguridad para la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos humanos y se aprueban las normas de coordinación y funcionamiento para su uso en humanos (Royal Decree 1301/2006 of 10th November, on setting standards of quality and safety for the donation, procurement, evaluation, processing, preservation, storage and distribution of human tissues and cells, and on approving coordination and operation rules for its human application)
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Royal Decree 1301/2006, as mentioned above in 3.1.
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Royal Decree 1301/2006, as mentioned above in 3.1.
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	

SWEDEN	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	National law effective from 01/07/2008 (The law (2008:286) of quality and safety when handling human tissues and cell). Regulations from the National Board of Health and Welfare published 15/12/2008 (SOSFS 2008:22 and 2008:24) Medical Products Agency´s Provisions (LVFS 2008:12) regarding human tissues and cells for use in medicinal products
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	National law (2008:286) effective from 01/07/2008, amendment 01/01/09 (The law (2008:286)of quality and safety when handling human tissues and cell). Regulations from the National Board of Health and Welfare published 15/12/2008 (SOSFS 2008:22 and 2008:24). Medical Products Agency´s Provisions (LVFS 2008:12) regarding human tissues and cells for use in medicinal products
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	National law (2008:286) effective from 01/07/2008, amendment 01/01/09 (The law (2008:286)of quality and safety when handling human tissues and cell). Regulations from the National Board of Health and Welfare published 15/12/2008 (SOSFS 2008:22 and 2008:24). Medical Products Agency´s Provisions (LVFS 2008:12) regarding human tissues and cells for use in medicinal products
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	No
specify difficulties	
TURKEY	
3.1 Has Directive 2004/23/EC been transposed into national law?	no
Name of the implementing measure	
Expected transposition of the directive 2004/23/EC	01/12/2009
3.2 Has Directive 2006/17/EC been transposed into national law?	no
Name of the implementing measure	
Expected transposition of the directive 2006/17/EC	01/12/2009
3.1 Has Directive 2006/86/EC been transposed into national law?	no
Name of the implementing measure	
Expected transposition of the directive 2006/86/EC	01/12/2009
3.4 Where there any difficulties with the transposition of the Directives?	Yes

specify difficulties	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.)
UNITED KINGDOM	
3.1 Has Directive 2004/23/EC been transposed into national law?	yes
Name of the implementing measure	Directive 2004/23/EC was fully implemented into UK law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Directions 001/2006, 002/2007 and 004/2007 given under the Human Tissue Act 2004.
Expected transposition of the directive 2004/23/EC	
3.2 Has Directive 2006/17/EC been transposed into national law?	yes
Name of the implementing measure	Directive 2006/17/EC was fully implemented into UK law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Directions 001/2006, 002/2007 and 004/2007 given under the Human Tissue Act 2004.
Expected transposition of the directive 2006/17/EC	
3.1 Has Directive 2006/86/EC been transposed into national law?	yes
Name of the implementing measure	Directive 2006/86/EC was fully implemented into law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Directions 001/2006, 002/2007 and 004/2007 given under the Human Tissue Act 2004.
Expected transposition of the directive 2006/86/EC	
3.4 Where there any difficulties with the transposition of the Directives?	Yes
specify difficulties	There have been two main areas of difficulties in the UK 1) The UK transposition of the Directives has meant that procurement organisations and distributors of acellular material need to be licensed. This created a large workload for the HTA and difficulties for the TE involved. 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 testing e.g. HLA typing and/or microbiological testing

4. ACCREDITATION, DESIGNATION, AUTHORISATION or LICENSING (Article 6)

AUSTRIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	03/2008 as tissue establishment (in former times pharmaceutical org)
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Tissue establishments & Procurement centers have to be autorised by the CA by completing and submitting defined forms. Inspection and licensing will follow
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The role of the inspection is to prove if the requirements of the directives are fulfilled
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	

Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
BELGIUM	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	1988
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	After reception of an application for an accreditation or for a renewal of an existing accreditation from a tissue establishment, the establishment is inspected by the Agency. In function of the result of the inspection the accreditation is awarded.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Essential.

4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Preparation processes are inspected during the general inspections of tissue establishments.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	3
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	19
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	5
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	3
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	12
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	4
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	33
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	0

4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	Amnion membrane: 4 Cell therapy: 5 Hepatic cells: 1 Keratinocytes: 3 Pancreatic cells (cells and islets of Langerhans): 2 Tympano-ossicular allografts: 4
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	0
BULGARIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	Since 1 of January 2004 and then amended at 1 of January 2007 according to Organ, tissue and cell transplantation act and its relevant ordinances (with already transposed Directives requirements).
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Health or tissue establishments must apply with required set of documentation to the Executive Agency of Transplantation for receiving authorization for specific tissues/cells activity they whish to perform. The set of documentation includes but is not limited to: Court registration and authorization by regional health centre or Ministry of health as a health establishment, SOP,s manual and Rules of organization, diplomas of people working in the establishment et.c.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	After an documental assessment of the applicant is performed and the documentation is approved to comply with legislative requirements then a planed inspection for authorization is performed to verify compliance with Organ, tissue and cell transplantation act and its relevant ordinances (with already transposed Directives requirements).
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Every particular preparation process is authorized based on conditions and resources that given health establishment demonstrates by documental system (SOP), training of the personal and facilities suitable for this process et.c.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes

How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	2
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	2
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	2
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	5
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	12
Total number accredited as of 31/12/2008.	19
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	0
Total number accredited as of 31/12/2008. Please specify the type of establishment.	1 Hepatocyte cell bank
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	HPC Authorising Authority-Executive Agency of Transplantation 1 unit for one patient Country of origin-Germany
CROATIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	Authorisation process of TE partially started in 2007
explain why	

4.2 How is the accreditation, designation, authorisation or licensing system organised?	Department for inspection and blood, tissue and cells monitoring is technical units responsible for the preparation and organisation of the licensing procedure. The licensing process is based on the verification visit to TE (inspection), carried out by the Committee (inspector and expert(s)) in order to assess whether the TE fulfill the licensing criteria. According to their positive opinion the minister assign the licence to TE for the period of 4 years.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	See in 4.2
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Yes (partially) - see in 4.2.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	3
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	0
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	3
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1

Total number accredited as of 31/12/2008.	0
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
CYPRUS	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	November 2008
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Aplication-Dossier Submission-Inspection-Authorisation granded
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Prerequisite to authorisation. Three inspectors appointed. Summoning of experts if required.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Dossier submission and approval. Confirmed by inspection
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons,	No

fascia, etc) accredited?	
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	5
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	12
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	

4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	Haematopoietic Peripheral and Bone Marrow Stem Cells, Lymphocytes(DLI), 28, Cyprus
CZECH REPUBLIC	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	Since when? 18th October 2008 the Act no. 296/2008 Coll. entered into force. The current accreditations are accepted till 18th April 2009 in conformity with our older heath service legislation. When the application for the authorisation is submitted to the State Institute for Drug Control till this date the current accreditation is accepted till the decision of the State Institute for Drug Control.
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Steps: - The application for the authorisation is submitted to the State Institute for Drug Control according requirements stated by the Decree no. 422/2008 Coll. (documentation and data must be submitted to confirm that the applicant meets provisions of the Act no. 296/2008/Coll. and of the Decree no. 422/2008 Coll.). - Documentation and data submitted are assessed; if necessary, the applicant is asked to complete them, explain etc.. - The inspection in the place by inspectors of the State Institute for Drug Control; the deficiencies discovered are described in the inspection protocol. 5. The applicant is asked to solve and withdraw deficiencies and to send the report on it. 6. The decision of the State Institute for Drug Control - the authorisation is issued or the application is refused.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Control of activities and system of the applicant created to reach the compliance with the legislation; also compliance of current practice with the documentation and data received with application.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Included in the authorisation procedure (see item 4.2.)
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	2
Total number accredited as of 31/12/2008.	19
4.7 Are all Ophthalmic establishments (cornea, sclera, etc)	Yes

accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	2
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	4
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	2
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	28
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	2
4.13 Are other types of establishments accredited?	
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
DENMARK	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	April 2007
explain why	

4.2 How is the accreditation, designation, authorisation or licensing system organised?	Organisations fulfilling the definition of a tissue establishmnt are required to apply to the Agency for a lic. of their specific on-site activities.The application forms at the Agency website are additionally relevant for re-applications and notification of significant changes.Thereafter the application is subject to an internal review process and where it's satisfactory completed it's transferred to the insp. group for the site insp. phase.The latter is prioritised on the basis of tissue/cell type,resources and other insp. work commitments.After the site insp.–with the insp. report and evaluation of any non-compliances- the inspector provides a summary statement in the file as to whether the licence can be issued according to the application.Where favourable the file transfers to the admin. section for a comparison of the insp. report with the application and the issuing of the licensing certificate, for a max. of 2 years.Relevant internal SOPs within the Agency define these phases
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The role of inspections is a desk-based and on-site assessment and control of compliance with the EU tissues and cells directives, as specified by the transposed national regulations, performed by officials of the Community Competent Authorities. This approach provides confidence to others on the quality and safety of different human tissues and cells for therapeutic applications. The mutual recognition of these “licensed” tissue establishments in different countries encourages and simplifies their availability in other EC countries.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	The specialised and routine processing systems are evaluated as part of the on-site inspection of the site premises, under their responsibility.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	12 including 3 testing centres
Total number accredited as of 31/12/2008.	11 including 3 testing centres
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.8 Are all Vascular establishments (heart valves, vessels, etc)	Yes

accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	67
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	7 including 4 testing centres
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	1
Total number accredited as of 31/12/2008. Please specify the type of establishment.	chondrocytes 2 lymphocytes 1 testing centres 3 sperm banks 3
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	corneas, danish medicines agency, 18, USA. amnion, Danish agence, 2, Prague
ESTONIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	01.01.2009 Tissue establishments should submit their applications before 01.04.2009
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Licensing is provided by State Agency of Medicines. Applicants have to provide Agency with needed data shown in regulation. In licensing process Agency evaluates application dossier and conducts site inspection to verify that the establishment complies with requirements of national law and regulations and data provided in dossier. If the establishment is in compliance with requirements laid down in national law and data provided in dossier Agency will issue a licences specifying the processes and types of tissues, cells or organs that had been licensed.

4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The role of inspections is to verify the correspondence of the applicants conditions to the regulation and data provided in dossier.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	Tissue establishments are licensed fully in one step covering preparation processes and other areas of activities.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.10 Are all Cord blood establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0

4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	3
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	0 Law does not forsee the distribution under the agreement of CA.
FINLAND	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	1st June 2007
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	An application for license -> Pre-approval on-site inspection by CA -> licensing of tissue establishment
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Pre-approval on-site inspection is required before licensing
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	Donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells are licensed as such. Each TE defines type of cell processing e.g. aseptic procurement, separation, consentration, selection, cutting, cold/cryo/glycerol preservation etc. All these preparation processes are inspected during regular inspections.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1

4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	24
Total number accredited as of 31/12/2008.	24
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	2
Total number accredited as of 31/12/2008.	2
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	11
Total number accredited as of 31/12/2008.	11
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	24
Total number accredited as of 31/12/2008.	24
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	No agreement given for direct distribution.
FRANCE	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes

since when in place	-since 1999 for tissues - since 2001 for cells -since 1987 for ART
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	1) For tissues and cells (excepting ART activities) The application is sent to the general director of the French Health products and safety Agency with a dossier which includes all requirement needed for an authorisation 2) ART: Each Regional Hospitalisation Agency authorises ART activities after having consulted the ABM. The authorisation applies for a period of 5 years. All the information about establishments authorised for ART is available on the ABM website
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The inspectors check and review on site the information and data that have been submitted in the application dossier and the respect of the regulations. They give approval or not in the conclusion written in the final inspection report. This conclusion is taken into account to grant the above-mentioned authorisation. In the ARTT activities area, the authorisation involves a control of the compliance to general and specific requirements (full on-site visit by inspectors and if appropriate 5 years-report of activities and results)
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	The applicant may apply for the authorisation of preparation process. He sends his authorisation request to the director of the Health and safety Agency. The information and data he gives are assessed by experts working on each field of competency.The main points assessed are : - starting materials (cells and tissus procured) - the preparation process , - quality control of the finished product - information on viral safety Informations on non-clinical data (safety and mechanism of activity of tissues and cells) and clinical data (data supporting the therapeutic indication) are also take into account. The authorization is given by the director of the Health and safety Agency four months after the registration of the file; In the ART activities area, the authorisation indicates which activities among the 7 biological activities are specifically authorised : 1. Sperm preparation for IUI 2. IVF and ICSI 3. Oocyte donation 4. Sperm donation 5. Embryo donation 6. Gametes and germinal tissue cryopreservation 7 embryo preservation for embryos with parental plan These specifically authorised activities are considered to be the “ART processes”
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes

How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	9
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	9
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	211
Total number accredited as of 31/12/2008.	219
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1 (for tissues)
Total number accredited as of 31/12/2008.	55 (29 for tissues and 26 for cells)
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	1 (myeloblaste cells)
Total number accredited as of 31/12/2008. Please specify the type of establishment.	4 : -modified genetical cells : 1- keratinocyte cells : 2 -chondrocyte cells : 1 -myeloblaste cells :1
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
GERMANY	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	August 1st, 2007
explain why	

4.2 How is the accreditation, designation, authorisation or licensing system organised?	a) § 20b AMG (German Medicinal Products Act) and § 20c AMG permission from the federal state authorities for the processing, conservation, storage. In addition, the federal state authorities are responsible for the inspections. b) § 21a AMG authorisation from the Paul-Ehrlich-Institut for placing the medicinal products on the market.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The § 20b AMG and § 20c AMG permission is based on an inspection process.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	These data should be available from the german federal competent authority Deutsches Institut für Medizinische Dokumentation und Information (DIMDI). In addition, the federal state authorities of the Laender need to be asked.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	90
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	36
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	26
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	200
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.10 Are all Cord blood establishments accredited?	No

How many are not yet accredited?	5
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	Based on the German Medicinal Products Act reproductive tissues and cells establishments do not need an authorisation from the Paul-Ehrlich-Institut for semen and egg cells for placing on the market. They only need a permission from the federal state authorities.
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	number unknown yet
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	number unknown yet
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
GREECE	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	No
since when in place	
explain why	Not Yet. Because we are in the process of developing the necessary legal system and adapting to the technical-economical needs of such measures.
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Not in place yet.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Not yet described. There is also a need for training inspectors for that cause.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	Pending in the new directive
4.4 Overview of tissue/cells establishment	

4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	all
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	No

How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
HUNGARY	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	The regulation of Government on licensing health care providers was approved in 2003 (96/2003 Gov.Decree). This regulation gives the basis of the health care providers, including tissue and cell banks, therefore the process of licensing is unified for all the health care providers
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	According to the 96/2003 Gov. Dec. the license is given by the regional authority of the NPHMOS under the rules of that regulation.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	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/requirements". 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).
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	According to the Min. Dec. 18/1998 there is an agreement between the tissue and cell bank and the health service provider which collects tissues and cells, in which has to determine the features of tissues and cells, samples and the features of procedures under collection.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	2
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	2

4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	5
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	3
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	5
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	22
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	3
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	No data.
IRELAND	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	From the 7th April 2006 following transposition of National Legislation.
explain why	

4.2 How is the accreditation, designation, authorisation or licensing system organised?	All tissue establishments are required to submit an application for tissue establishment authorisation to the Irish Medicines Board. Full on-site inspections to assess the status of compliance with the Tissues and Cells Directives are performed following receipt of application and prior to authorisation of the tissue establishment.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Full on-site inspections are performed prior to the authorisation of Tissue Esablishments.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Preparation processes are assessed during on-site tissue establishment inspections and are documented on the tissue establishment authorisation which is issued to Tissue Establishments when they have demonstrated compliance with the Tissues and Cells Directives.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	Not applicable - There are no skin establishments in Ireland.
How many were accredited between 1/1/2008 and 31/12/2008?	Not applicable - There are no skin establishments in Ireland.
Total number accredited as of 31/12/2008.	Not applicable - There are no skin establishments in Ireland.
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	Not applicable - There are no individual opthalmic establishments in Ireland.
How many were accredited between 1/1/2008 and 31/12/2008?	Not applicable - There are no individual opthalmic establishments in Ireland.
Total number accredited as of 31/12/2008.	Not applicable - There are no individual opthalmic establishments in Ireland.
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	Not applicable - There are no individual vascular establishments in Ireland.
How many were accredited between 1/1/2008 and 31/12/2008?	Not applicable - There are no individual vascular establishments in Ireland.
Total number accredited as of 31/12/2008.	Not applicable - There are no individual vascular establishments in Ireland.
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	4
How many were accredited between 1/1/2008 and 31/12/2008?	1

Total number accredited as of 31/12/2008.	1
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1 - Procurement Organisation
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	7
Total number accredited as of 31/12/2008.	7
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	One Tissues and Cells Storage Company was authorised in 2008. Two procurement organisations are in the process of being authorised.
Total number accredited as of 31/12/2008. Please specify the type of establishment.	One Tissues and Cells Storage Company was authorised in 2008. Two procurement organisations are in the process of being authorised.
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	None
ITALY	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	authorisation and accreditation are made by the regions on the basis of minum requirements
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Each regions has its own system Since 2007 the National Blood Centre participates to the institutional accreditation system performed by the National Transplant Centre in regard of the Peripheral Haematopoietic Stem Cells (PHSCs) collection and processing Units. In regard of the Cord Blood Banks the accreditation system is not yet in place. The system is in charge of regional health authorities, which have to comply with nationally established authorisation requirements and regionally established accreditation requirements; the latter shall have to comply with national guidelines issued by the National Blood Centre and the National Transplant Centre. The inspection system will be updated together with realization of the new authorisation/accreditation system, applying the Legislative Decree 6 November 2007, n.191, which transposed the European Directive 2004/23/EC.

4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	4
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	4
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	14
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	4
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	108
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	2
Total number accredited as of 31/12/2008.	18
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	341
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	2
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	

Total number accredited as of 31/12/2008. Please specify the type of establishment.	1 amniotic membrane
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
LITHUANIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	2007
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	The licensing of Tissue Establishments is organised in accordance with valid legal acts, i.e., following the orders of the Minister of Health: LAW ON HEALTH SYSTEM; LAW ON HEALTH CARE INSTITUTIONS; the order of the Minister of Health CONCERNING THE LIST OF LICENSING OF PERSON HEALTH CARE CERVICES; the order of the Minister of Health ABOUT SPECIFIC REQUIREMENTS FOR PERSONEL WHO PERFORMS HUMAN TISSUES AND CELLS PROCUREMENT, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION, AND REQUIREMENTS FOR EQUIPMENT NEEDED FOR HUMAN TISSUES AND CELLS PROCUREMENT, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	There are several institutions responsible for inspections, which control quality of health care services and their compliance with legal regulations: • State Patients' Fund • State Medical Audit Inspectorate 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 (control over compliance with licence conditions) • Hygiene Inspection
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Performed in accordance with valid legal acts.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.7 Are all Ophthalmic establishments (cornea, sclera, etc)	No

accredited?	
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	N/A
How many were accredited between 1/1/2008 and 31/12/2008?	N/A
Total number accredited as of 31/12/2008.	N/A
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
MALTA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	No
since when in place	
explain why	The responsible Regulatory Division is in the phase of establishing the necessary capacity building.

4.2 How is the accreditation, designation, authorisation or licensing system organised?	Not Applicable - the responsible Regulatory Division is in the phase of establishing the necessary capacity building.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	The responsible Regulatory Division is in the phase of establishing the necessary capacity building.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	Not applicable
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	Not applicable
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	One (1)
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	Not applicable
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	Not applicable
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	Two (2) cord blood procurement agencies
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	

4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	One (1)
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	Not applicable
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
NETHERLANDS	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	1 July 2007
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Licensing system; Establishments need to fill in the application form. After advise (after inspection) of the Health Care Inspectorate the Minister gives the license (executed by the CIBG)
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	See above (advise)
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	see answer 4.2.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons,	No

fascia, etc) accredited?	
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	

4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
NORWAY	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	July 1st 2008
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	The actual body applies for a licence thereby giving information on how they meet the demands set in National regulation. Norwegian Directorate of Health assess whether the information is in concordance with the regulation
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	To be answered by Norwegian Board of Health
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	The applicants describe their procedure and give references and/or descriptions on for how long the procedure has been in use and information on any unwanted reactions.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	3
Total number accredited as of 31/12/2008.	3
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes

How many were accredited between 1/1/2008 and 31/12/2008?	4
Total number accredited as of 31/12/2008.	4
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	11
Total number accredited as of 31/12/2008.	11
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	8 test laboratories 1 ex-vivo cell laboratory
Total number accredited as of 31/12/2008. Please specify the type of establishment.	Plese see above
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	0
POLAND	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	2007
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Tissue establishments are required to send their application for site authorisation to the Competent Authority for evaluation. Thereafter it was internally reviewed by the Competent Authority using a check list for compliance with the expected systems and requirements for a tissue establishment. The Competent Authority organize on-site inspection. After the inspection the Competent Authority prepared an audit report. The Competent Authority submitted a summary and overall recommendation to the Ministry of Health, via the National Transplant Council. Certificates of authorisation for specific sites were prepared and issued by the administrative offices of the Ministry of Health, with a copy sent to the CA for their records.

4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Inspection is an integral part of licensing of tissue establishments. The Competent Authority checklist with the pre-evaluation of the tissue establishment supporting documentation formed the basis of the inspection programme at the site audit. After the inspection the Competent Authority prepares an audit report for the responsible person to undersign – to confirm the written non-compliances and their commitment to fulfilling the transposed Regulations.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Preparation processes are described by tissue bank in documentation sent for site authorisation. They are chequed during on-site inspection.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	2
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	2
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	3
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	10
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	0

How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	3
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	- Chondrocyte bank - 1 - Pancreatic islets bank - 1
Total number accredited as of 31/12/2008. Please specify the type of establishment.	- Chondrocyte bank - 1 - Pancreatic islets bank - 1
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	0
PORTUGAL	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	March 2009 - Law n.º 12/2009; For reproductive cells, the regulation of Law 32/2006 of 26 July was published on February 11, 2008. On May 2008 CNPMA defined and approved the terms for authorisation of centres where assisted reproduction techniques are administered, and of centres where gametes or embryos are preserved.
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	All tissue establishments, except for reproductive cells, should be authorized by ASST after documentation analisys and inspections. For reproductive cells, the establishments are authorized by the Conselho Nacional de Procriação Medicamente Assistida, under documents analysis and inspections. Regarding reproductive cells, assisted reproduction techniques can only be administered at public or private centres expressly authorised for this purpose by the Minister of Health (Law 32/2006 of 26 July). Public and private centres must submit the application to the Regional Offices of the Ministry of Health, which requests to CNPMA to issue an opinion, which is binding if negative. Afterwards the Minister of Health decides whether to provide or not the authorisation.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	All tissue banks should be inspected by ASST (except reproductive cells) Regarding reproductive cells, the Executive Law 5/2008 of 11 February determines that the Ministry of Health administrative body for Health Inspections (Inspecção-Geral das Actividades em Saúde) is responsible for inspections and auditing to assess, public and private, assisted reproduction techniques centres, under the guidance of CNPMA. The CNPMA shall also assure initial and permanent training for clinical and laboratory inspectors.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes

describe procedure	
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	17
How many were accredited between 1/1/2008 and 31/12/2008?	4
Total number accredited as of 31/12/2008.	4
4.12 Are all Multi-tissue establishments accredited?	No

How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	Zero
ROMANIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	2006
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	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. The analysis of the dossier is followed by an inspection of the tissue establishment done by the National Transplant Agency together with the Department of Control in Public Health. Then the Agency makes proposals for accreditation to the Ministry of Health. The accreditation is done through a Minister of Health's Order based on the proposals of the Agency.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	As we described above, the conclusions of the inspection and the dossier are the two decisive factors for the accreditation of the tissue establishments.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	The dossier for accreditation includes the description of the preparation procedures, all being validated procedures. According to the Romanian legislation, there is another institution responsible for the accreditation, validation and clinical application of the procedures – the Medical College of Physicians.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	4
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes

How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	2
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	1
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	3
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	6
Total number accredited as of 31/12/2008.	14
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	0
Total number accredited as of 31/12/2008. Please specify the type of establishment.	1 Pancreatic Cells
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	0
SLOVAKIA	

4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	The requirement for authorisation of tissue banks was introduced in the 80th (more than 20 years ago). According to Law 282/2006 all the previously existing TEs had to request their new authorisation latest April 7th, 2007 from the CA
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Authorisation is issued by the Competent Authority (CA) upon request of the TE. The TE is obliged to submit an official request for authorisation to the CA. If the TE is able to fulfill all the legal requirements, the authorisation is granted.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	So far the inspection system is in the phase of preparation. It is expected, that the designated CA for inspections will become the State Institute for Drug Control (SUKL).
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	It is in the phase of preparation. It is expected, that the designated CA for authorisation of preparation processes will become the State Institute for Drug Control (SUKL).
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	2
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	1
How many were accredited between 1/1/2008 and 31/12/2008?	

Total number accredited as of 31/12/2008.	6
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	7
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	2
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	1 processing center - autologous cell culture laboratory
Total number accredited as of 31/12/2008. Please specify the type of establishment.	1 processing center - autologous cell culture laboratory
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
SLOVENIA	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	Since 26th July 2008, when Rules on conditions for granting permission for performing of activity of supply with human tissues and cells came into force.
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Applicant has to apply for authorisation. Authorisation procedure includes the preauthorisation inspection at the applicant site performed by a team of nominated inspectors. Applicants, who already operate on the field of tissue and cells before new legislation came into force, had to apply for authorisation until 26th Oct, 2008.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The role of inspection is to determinate if applicant fulfils the requirements determined by legislation.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	Preparation processes (within meaning the type of manipulations of tissue and cells) are identified during preauthorisation inspection and they are listed on the authorisation. Preparation processes are not assessed in details and there is no requirement for Preparation Process Dossier.
explain why	

4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	3
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	No
How many are not yet accredited?	2
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	1 (estimation)
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	2 (1 accredited in 2009)
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	5 (2 accredited in 2009)
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	3 (all accredited in 2009)
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	0
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	0
How many were accredited between 1/1/2008 and 31/12/2008?	0

Total number accredited as of 31/12/2008.	0
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	1 (tissue engineered product from cartilage; accredited in 2008) 1 (tissue engineered fibroblasts from skin; accredited in 2009)
Total number accredited as of 31/12/2008. Please specify the type of establishment.	1
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	0
SPAIN	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	As the executive powers on healthcare have been devolved to the Autonomous Communities, these are responsible for the accreditation, designation, authorisation, or licensing on their corresponding tissue establishments. Although there might be some regional variability in the procedure due to regulatory and organisational differences, there is a binding common procedure (RD 1277/2003) and specific requirements (RD 1301/2006) to fulfil. Authorisations are to be granted for a specific activity and type of cell or tissue. The validity of the authorisations is to extend over a period between two and four years, and may be renewed after the period of validity, on verification of the conditions that led to its granting. Under no circumstances authorisation shall be extended automatically. Any substantial changes in conditions that prompted the authorisation are to be reported to the relevant competent authority and might cause its revision or revocation.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	It depends on the Autonomous Community involved. According to the regulation, authorisations whether for the operation or for any modifications on structure, management or healthcare provision, are to be granted by the Autonomous Communities Competent Authorities, after the verification of the fulfilment of the mandatory requirements. In this sense, the Autonomous Communities have been endorsed to develop internal procedures for the authorisation on the installation, operation, modification or closure of any healthcare facilities, specifying the mandatory process and documentation. Although the authorization is generally based on inspections, in some regions the authorization is made through documentation analysis.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes

describe procedure	It is a mandatory requirement for authorisation of Tissue Establishments (TE) detailed in annex I.3 of the RD 1301/2006. Some of the requirement are: - A systematic and effective validation system of all critical processes has to be in place and has to be documented. - TEs are not authorised to introduce any change without prior validation and documentation of such modification. - All processing activities are to be assessed periodically, so expected results can be assured.
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	14
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	36
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	22
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	12 (Heart Valves) - 16 (Vessels) - In some cases both are processed in the same TE
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	21
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	10
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	34
4.13 Are other types of establishments accredited?	

How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
SWEDEN	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	No
since when in place	
explain why	The authorisation process started December 1st 2008 when tissue establishments applied for authorisation to the National Board of Health and Welfare and the Medical Products Agency. Applications are now being evaluated and complementary information are requested. Authorisations will be granted in june/july 2009. The National Board of Health and Welfare received applications from the following tissue establishments: 9 multi tissue (including vascular) 24 Musculo-Skeletal 22 Reproductive cells 7 Haematopoietic Stem cells (HSC) including cord blood 2 skin 2 Ophthalmic 2 others (complementary information requested)
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Temporary certifications will be granted based on information given at application.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	Extended certification is based on result of supervision. Supervision will begin during the year of 2009.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	See 4.1
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.7 Are all Ophthalmic establishments (cornea, sclera, etc)	No

accredited?	
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.10 Are all Cord blood establishments accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	See 4.1
How many were accredited between 1/1/2008 and 31/12/2008?	None, as the system was not yet in place.
Total number accredited as of 31/12/2008.	None, see 4.1
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	Unknown.
TURKEY	

4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	No
since when in place	
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	There is not any a system of accreditation, designation, authorisation or licensing in our country.
4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	Yes
describe procedure	
explain why	
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0
Total number accredited as of 31/12/2008.	17
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	4
Total number accredited as of 31/12/2008.	31
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	4

Total number accredited as of 31/12/2008.	5
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.12 Are all Multi-tissue establishments accredited?	No
How many are not yet accredited?	
How many were accredited between 1/1/2008 and 31/12/2008?	
Total number accredited as of 31/12/2008.	
4.13 Are other types of establishments accredited?	No
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	
Total number accredited as of 31/12/2008. Please specify the type of establishment.	
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	
UNITED KINGDOM	
4.1 Do you have a system of accreditation, designation, authorisation or licensing of tissue establishments in place?	Yes
since when in place	The HTA has a system for licensing tissue establishments and procurement organisations. The HTA began licensing tissue establishments on 1 April 2006 and licensing of procurement organisations began on 5 July 2008.
explain why	
4.2 How is the accreditation, designation, authorisation or licensing system organised?	Applicants apply for a licence via completion of an online application form. The HTA carries out a desk based evaluation (Phase 1 inspection) of the application form, by assessing their compliance with minimum standards. The standards were developed from the requirements set out in Directives 2004/23/EC, 2006/17/EC and 2006/86/EC. Upon completion of the evaluation by the HTA a decision to grant a licence is made. In accordance with the Directives a site inspection (Phase 2 inspection) is carried out every two years for all tissue establishments. The Phase 2 inspections are used to support initial licensing decisions in addition to ensuring that the compliance report (similar to a Tissue Establishment Dossier) accurately reflects all practices, procedures, premises, equipment, quality management and governance systems at the establishment. Regulatory enforcement action may be imposed as a result of either a Phase 1 or Phase 2 inspection, if warranted.

4.3 What is the role of inspections in the accreditation, designation, authorisation or licensing system?	The HTA defines inspection as a process encompassing desk-based review, site visit assessment and analysis of relevant information to evaluate an establishment's compliance with the minimum regulatory standards. Desk-based evaluations are described as Phase 1 inspections and site visit assessments are described as Phase 2 inspections. Phase 2 inspections are used to gather information at site. Both Phase1 and Phase 2 inspections lead to licensing decisions. The HTA targets Phase 2 inspections at those establishments deemed to be at highest risk for regulatory non-compliance. The primary sources that inform the framework for regulatory risk are the Human Tissue Act 2004 (HT Act) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regs) The legislation is supported by other documents developed by the HTA including codes of practice, Directions and licensing standards. The HTA uses the above in addition to the original application form to develop a risk based approach to inspection scheduling. This risk based approach ensures that those establishments at greatest risk of non-compliance with relevant legislation are inspected first. Site inspections are used to assure ourselves that: 1)all TEs have suitable premises, facilities, equipment and staff 2)a suitable quality management system is in place and includes all relevant SOPs, donor selection documentation, internal audit records, records of consent, training and reference manuals, reporting forms, traceability records, validation records and disposal records 3)that all processes and procedures (including procurement, testing, processing, storage distribution, import and export) are being carried out according to the Q&S Regs. 4)that the Responsible Person meets the legislative requirements and is a suitable individual for the role and has mechanisms in place to enable licensed activities to be carried out according to the Q&S Regs.
4.4 Is there an authorisation of preparation processes system in place (Article 6(2))?	No
describe procedure	
explain why	As required by the Directives 2004/23/EC, 2006/17/EC and 2006/86/EC, a HTA inspection includes the assessment of preparation processes. However, we do not individually authorise each tissue and cell preparation process. During an inspection the TE will be expected to supply inspectors with documented evidence that all processing steps are suitable, validated and can demonstrate that the quality and safety of the tissues and / or cells is assured. The information gathered during a site visit inspection provides all the necessary information to adequately assess the tissue establishment processes. Where necessary, we may take regulatory action to ensure that processes that do not meet regulatory requirements are stopped or changed.
4.4 Overview of tissue/cells establishment	
4.5 Are all skin establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	0

Total number accredited as of 31/12/2008.	9
4.6 Are all Musculo-Skeletal establishments (bone, tendons, fascia, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	13
Total number accredited as of 31/12/2008.	42
4.7 Are all Ophthalmic establishments (cornea, sclera, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	5
4.8 Are all Vascular establishments (heart valves, vessels, etc) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	1
Total number accredited as of 31/12/2008.	3
4.9 Are all Haematopoietic Stem cells (HSC) establishments (other than cord blood) accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	4
Total number accredited as of 31/12/2008.	9
4.10 Are all Cord blood establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	6
Total number accredited as of 31/12/2008.	13
4.11 Are all Reproductive cells establishments (semen, egg cells) accredited?	No
How many are not yet accredited?	Not applicable
How many were accredited between 1/1/2008 and 31/12/2008?	Not applicable
Total number accredited as of 31/12/2008.	Not applicable
4.12 Are all Multi-tissue establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008?	20
Total number accredited as of 31/12/2008.	162
4.13 Are other types of establishments accredited?	Yes
How many were accredited between 1/1/2008 and 31/12/2008? Please specify the type of establishment.	18 Islets of Langerhans Cartilage Chondrocytes Cells for ATMP Stem cell lines
Total number accredited as of 31/12/2008. Please specify the type of establishment.	22 Islets of Langerhans Cartilage Chondrocytes Cells for ATMP Stem cell lines
4.14 How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Article 6(5) during 2008?	None.

5. THIRD PART AGREEMENTS (Article 24)

AUSTRIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
BELGIUM	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
BULGARIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
CROATIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
If YES, under which of circumstances:	
Others (specify)	
CYPRUS	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes

If YES, under which of 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
Others (specify)	
CZECH REPUBLIC	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	where tissue establishment entrusts procurement of tissues and cells to a procurement establishment (for processing these tissues and cells) where tissue establishment entrusts the laboratory examination of the donor to diagnostic laboratory
DENMARK	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
ESTONIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
FINLAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
FRANCE	

5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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; other
Others (specify)	Does not apply to ART sector
GERMANY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
GREECE	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
If YES, under which of circumstances:	
Others (specify)	
HUNGARY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of circumstances:	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party
Others (specify)	
IRELAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
ITALY	

5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
LITHUANIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
MALTA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of circumstances:	other
Others (specify)	Where procurers acquire cells (umbilical cord blood) in Malta, which is subsequently processed and stored by laboratories and mother companies in other EU Member States.
NETHERLANDS	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
NORWAY	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
If YES, under which of circumstances:	
Others (specify)	
POLAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes

If YES, under which of 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
Others (specify)	
PORTUGAL	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
If YES, under which of circumstances:	
Others (specify)	
ROMANIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
If YES, under which of circumstances:	
Others (specify)	
SLOVAKIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
SLOVENIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of circumstances:	where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
Others (specify)	
SPAIN	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	
SWEDEN	
5.1 Have tissue establishments in your Member State notified	yes

third party agreements?	
If YES, under which of 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
Others (specify)	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.
TURKEY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of circumstances:	where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
Others (specify)	
UNITED KINGDOM	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
If YES, under which of 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
Others (specify)	

6. REPORTING OBLIGATIONS (Article 10)

AUSTRIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	Not available until now
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
BELGIUM	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	The dead line for submitting annual reports is April 30 2009. 5 TE already, submitted an annual report
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	

If yes, please provide us the register web link.	www.fagg-afmps.be
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	
establishments	Yes
Cord blood banks	Yes
Others	Yes
6.5 others	Amnion membrane Cell therapy Hepatic cells Keratinocytes Pancreatic cells (cells and islets of Langerhans) Tympano-ossicular allografts
6.5 please specify no answers	
BULGARIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	All.
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	www.bgtransplant.bg
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	www.bgtransplant.bg
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	Yes
6.5 others	1 Hepatocyte cell bank.
6.5 please specify no answers	
CROATIA	

6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	ALL
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	www.mzss.hr/hr/programi_i_projekti/unaprijedenje_zdravstvenih_usluga/transplantacijski_program
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	No
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
CYPRUS	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	0
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	http://www.moh.gov.cy/moh.nsf/medpub_en/medpub_en?OpenDocument
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	http://www.moh.gov.cy/moh.nsf/medpub_en/medpub_en?OpenDocument
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue	Yes

establishments	
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
CZECH REPUBLIC	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	ALL TE
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	In applications for authorisation submitted after the 18th October 2008 we ask for web links for reports of individual tissue establishments.
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	WWW.MZCR.CZ
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
DENMARK	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	Eighty eight tissue establishments submitted their annual reports for 2007 to our Agency.
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	

6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	HTTP://WWW.LAEGEMIDDELSTYRELSEN.DK/1024/VISLSARTIKEL.ASP?ARTIKELID=13133,
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	Yes
6.5 others	Tissue establishments for chondrocytes, lymphocytes, testing infectious markers and commercial distributors of human bone substitutes.
6.5 please specify no answers	
ESTONIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	0
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	As the process of licecing is ongoing there are no licenced establishments in this moment.
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes

Others	
6.5 others	
6.5 please specify no answers	
FINLAND	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	63 (/65)
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	List of licensed TEs (only name of organisation) is available on website: http://www.laakelaitos.fi/instancedata/prime_product_julkaisu/laakelaitos/embeds/Myonnetyt_kudoslaitostoimiluvat_20090304.pdf
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	No
6.5 others	
6.5 please specify no answers	
FRANCE	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	For 2007 ART ctivities, the ABM collects and analyses the annual reports from 100% of the ART laboratories
6.3 Are these reports publicly available? (Article 10 (1))	Yes

If yes, report model web link	ART : -The model of the report is available on the ABM website. - The individual report from each centre is not available on a website. - the annual report of ABM is available on its website publishing the national ART activities each year. For tissues and cells the register is not yet publicly available - For the annual ABM report and the national data in ART : http://www.agence-biomedecine.fr/uploads/document/RAA-clinico-biologique-2007_vf.doc on the website of the Agence de la biomedecine as regards ART laboratories. For tissues and cells the register is not yet publicly available
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	http://www.agence-biomedecine.fr/uploads/document/AMP-biologique30062008.pdf
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
GERMANY	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	approximately 200
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	not yet
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue	Yes

establishments	
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
GREECE	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No
If no, why?	No registry available yet
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
HUNGARY	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	0
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	

6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No
If no, why?	The register is not publicly available, this is the "united register of health services" (EFRIR) – mainly statistical register, which contains the data of health care providers, including TE's and based on certificate given by regional offices of the NPHMOS, but this is not specific to the TE
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
IRELAND	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	18
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	http://www.imb.ie/EN/Blood-Tissues--Cells/Blood--Tissue-Establishments-.aspx
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes

Others	Yes
6.5 others	Tissues and Cells Storage Company is authorised and listed on Register as Tissue Establishment
6.5 please specify no answers	Not applicable.
ITALY	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	all
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	www.trapianti.ministerosalute.it
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	www.trapianti.ministerosalute.it
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	
LITHUANIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	6
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	EUROCET website: www.eurocet.org

If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	No
Assisted reproduction centres	No
establishments	Yes
Cord blood banks	Yes
Others	
6.5 others	
6.5 please specify no answers	Skin, Musculo-Skeletal, Ophthalmic, Vascular tissue establishments : they are not licensed yet Assisted reproduction centres: not accredited
MALTA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	None
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No
If no, why?	There are no authorised tissue establishments as yet.
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
NETHERLANDS	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No

6.2 How many tissue establishments submitted annual reports of their activities during 2008?	
6.3 Are these reports publicly available? (Article 10 (1))	
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	www.farmatec.nl
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes
Cord blood banks	Yes
Others	Yes
6.5 others	
6.5 please specify no answers	
NORWAY	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	0. The licencing procedure took place in 2008
6.3 Are these reports publicly available? (Article 10 (1))	
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes

Cord blood banks	
Others	Yes
6.5 others	Test laboratories
6.5 please specify no answers	
POLAND	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	23
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	www.kcbtik.pl
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	www.kcbtik.pl
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	No
establishments	No
Cord blood banks	Yes
Others	Yes
6.5 others	- Chondrocyte bank - Pancreatic islets bank
6.5 please specify no answers	1. assisted reproduction centers activities are not regulated 2. HPC establishments does not exists
PORTUGAL	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	http://www.asst.min-saude.pt/; http://www.chsul.pt/
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	

If yes, please provide us the register web link.	(The registry is not complete yet). http://www.asst.min-saude.pt/transplantacao/servicos/Paginas/transplanteouaplicacao.aspx ;http://www.saudereprodutiva.dgs.pt/ ;www.cnpma.org.pt
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	No
Assisted reproduction centres	
establishments	Yes
Cord blood banks	No
Others	
6.5 others	
6.5 please specify no answers	All the tissue/cell establishment part of this registry are authorized under previous laws and were not authorized under the directives. The tissue/cell establishments that are not included in this registry, some of them were never inspected or even submit the requirements to the Health Ministry. So, they will be included only after the authorization under the new law 12/2009, that transposes all Directives.
ROMANIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	All the accredited tissue establishments.
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	www.transplant.ro
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	www.transplant.ro – Minister's of Public Health Order no.1225/2008, Minister's of Health Order no. 534/2005. The Minister's of Health Order is updated every two years. The tissue establishments acrcredited between the orders are published on the site.
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	Yes
establishments	Yes

Cord blood banks	Yes
Others	No
6.5 others	
6.5 please specify no answers	
SLOVAKIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	20
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No
If no, why?	
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
SLOVENIA	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	No
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	2
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	http://www.slovenija-transplant.si/index.php?id=135&L=2
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	http://www.slovenija-transplant.si/index.php?id=135&L=2

If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
SPAIN	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	All TE authorized and with activity
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	HTTP://WWW.ONT.ES --> ESTADISTICA
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	http://www.ont.es/contenido.jsp?id_nodo=293&&&keyword=&auditoria=F AND HTTP://WWW.ONT.ES/DOCUMENTACION/PDF/INFORME_REGISTRO_%20DE_%20CENTROS_%2009Q1.PDF
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	No
establishments	Yes
Cord blood banks	Yes
Others	Yes
6.5 others	Centres authorised for Amnion are also included in the registe
6.5 please specify no answers	
SWEDEN	

6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	? Directives were not implemented so that annual reports could be submitted for 2008. Tissue establishments will start submitting annual reports of activities during 2009.
6.3 Are these reports publicly available? (Article 10 (1))	Yes
If yes, report model web link	Annual reports will be available when they have been submitted for 2009
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No
If no, why?	The authorisation process is not yet completed. It will be publicly accessible when authorisations have been granted.
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
TURKEY	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	All of them
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No
If no, why?	
If yes, please provide us the register web link.	
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue	

establishments	
Assisted reproduction centres	
establishments	
Cord blood banks	
Others	
6.5 others	
6.5 please specify no answers	
UNITED KINGDOM	
6.1 Do you have an annual report model on the activities of tissue establishments in your Member State? (Article 10(1))	Yes
6.2 How many tissue establishments submitted annual reports of their activities during 2008?	165 Reports have been received from TE only, which includes any smaller linked premises (satellites) that they manage.
6.3 Are these reports publicly available? (Article 10 (1))	No
If yes, report model web link	
6.4 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	Yes
If no, why?	
If yes, please provide us the register web link.	WWW.HTA.GOV.UK/LICENSING/LICENSED_ESTABLISHMENTS.CFM
If yes, Does the register include all the accredited, designated, authorised or licensed tissue establishments to date? Please specify which ones:	
Skin, Musculo-Skeletal, Ophtalmic, Vascular tissue establishments	Yes
Assisted reproduction centres	No
establishments	Yes
Cord blood banks	Yes
Others	Yes
6.5 others	Procurement organisations and distributors of acellular human material
6.5 please specify no answers	

7. INSPECTIONS (Article 7)

AUSTRIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	For initial accreditation by application
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	2
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or	

reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	2
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
BELGIUM	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

If yes, please describe	Inspections are carried out by officially designated members of the staff of the Federal Agency for Medicines and Health Products
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	No
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	30
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	2
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	0
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	0
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	1
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	12
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0

7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	0
7.3.11 How many regular inspections of cord blood banks were conducted?	4
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	0
7.3.14 How many regular inspections of other tissue establishments were conducted?	19
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
BULGARIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	There is established system of inspection since 2005 which was fortified during 2007 with a new ordinance specific for inspection of tissue/cell establishments and also ART centres. According to this ordinance every year there are organized planed inspections. Inspections are performed according to written plan approved by Executive Director of the Agency.
If no, please specify why not	

7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	3
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	5
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	1
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	12
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	7
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	1
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	1
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	1
7.3.11 How many regular inspections of cord blood banks were	2

conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	0
7.3.14 How many regular inspections of other tissue establishments were conducted?	1
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	1
If yes, how many regular inspections have been conducted in 2008?	5
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	1
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	yes
If yes, how many?	1
If no, how are preparation processes inspected?	
Please, specify other authorisation	
CROATIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Every two year regular control inspection is assigned and done by the health care inspection . Extra ordinary inspections may be performed in case of SAR or SAE ….
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	
Advanced therapies	

Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were	

conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	Three
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
CYPRUS	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Three Inspectors appointed to examine applications/dossiers and contact TEs to arrange inspections. One inspection annually and in case of SAR/SAE reporting
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	

7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	

If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection; on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
CZECH REPUBLIC	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	GMP Inspection planning principles are laid down by internal document PN-INS-018-1 of the State Institute for Drug Control. Follow-up inspection of tissue establishment or procurement establishment shall be conducted in the maximal interval 24 months. (the interval may be shortened based on the results of the previous inspection or on current situation; also in case of the serious adverse event and serious adverse reaction).
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	3
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	

7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no

If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection; on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
DENMARK	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Within the inspection group of the Agency the forward planner for the organisation of inspections considers various parameters (e.g. type of tissue/cells, outcome of previous inspection, size/location of specific site, complexity of systems, etc). The planner is subject to amendments (e.g. new applications, revised activities and resources) and revisions throughout the year. In 2008 the focus was directed to processing supplementary new applications, inspecting representative gynaecology units, some procurement sites and collating data for the annual report. Testing centres solely performing the testing of infectious markers of blood samples are required to be licensed by the Agency. Compliance with the donation and procurement requirements of the Regulations are examined when inspecting the site address of the tissue establishment. The type of tissue or cell, the specified activities, and other relevant data of all TE's, and their procurement sites, are maintained in a database.
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	
Others	Yes
Specify others	General medicine? The internal Agency activities for the inspection of other sector products (e.g. blood, medicines, etc) are similar in format and structure. Consequently the internal SOP's and support systems are linked, and separated, by the specialities of each sector. Inspectors for the tissues and cells sector typically have a background and knowledge in the pharmaceutical or blood sector, general medicine. This is further enhanced with internal/external training programmes and reviews with similar colleagues, to develop and maintain the inspection standards for the safety and quality of human tissues & cells.

7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	2
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	0
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	5
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	1
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	1
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	0
7.3.11 How many regular inspections of cord blood banks were conducted?	1
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	1 lymfocyte, 1 heart valve, 1 testing infectious markers
7.3.14 How many regular inspections of other tissue establishments were conducted?	3 (2 sperm bank, 1 testing)
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0

7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	1
If yes, how many regular inspections have been conducted in 2008?	0
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	0
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
ESTONIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Estonian State Agencie's Department of Biologicals is providing supervision of tissue establishments. Department has two employees who have passed EUSTITE courses for tissue establishment inspectors. Department's inspection scheme covers also blood. Routine inspections of tissue establishments are conducted once in two years as a full inspection. Additional non-routine inspections are scheduled on necessity bases (adverse events and reactions) on certain circumstances and in response, to application of tissue establishment to modify it's activities
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	
Advanced therapies	Yes
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no

7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	

If yes, how many initial inspections have been conducted in 2008?	no
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
FINLAND	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	All TE applicants are inspected before licensing. Licensed TEs are inspected at least every two years.
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	No
Others	No
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	28
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0

7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	26
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	0
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0 (11 HPC establishments were inspected in 2007)
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	0
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	0 (1 cord blood bank was inspected in 2007)
7.3.11 How many regular inspections of cord blood banks were conducted?	0
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	0
7.3.14 How many regular inspections of other tissue establishments were conducted?	0
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no

If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
FRANCE	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	The system is based on a : -scheduled and planned inspection every 6 months -risk based inspection New inspector is trained with regard to the SOP's in place within the Afssaps.He or she accompanies the senior inspector for several inspections and in the end there is an evaluation and qualification of the capacity of the new inspector to lead alone an inspection according with an internal SOP's. Concerning the inspection report, the inspector write an initial report with initial conclusion .The inspectee has to answer to the initial report within 15 days. After the evaluation of the response, a final report with a final conclusion is written, and the inspector can status on the application (approval or not)
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	1
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	4
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	2

7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	Impossible for the Agence de la biomedicine to answer to this question because the inspections are conducted by the local health Agencies at a regional level.
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	Impossible for the Agence de la biomedicine to answer to this question because the inspections are conducted by local health Agencies at a regional level.
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	Impossible for the Agence de la biomedicine to answer to this question because the inspections are conducted by local health Agencies at a regional level.
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	5
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	0
7.3.11 How many regular inspections of cord blood banks were conducted?	0
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	0
7.3.14 How many regular inspections of other tissue establishments were conducted?	40 (establishments (hospitals and clinics) which store et distribute tissus for end use)
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	3
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	0
If yes, how many regular inspections have been conducted in 2008?	1
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	3
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	yes

If yes, how many?	2
If no, how are preparation processes inspected?	
Please, specify other authorisation	
GERMANY	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	The responsible competent authorities of the Laender provide staff for regular inspections according to a work plan.There are committees of inspectors of the Laender 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).
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	- mainly the same inspectors. - common basic training. - common aspects of documentation. - but specific information and training for the different establishments and processing procedures regarding the different products.
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	number unknown. Responsibility of the competent authorities of the german federal Laender (number unknown).
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	none
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	number unknown
7.3.5 How many regular inspections in assisted reproduction	number unknown

centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	none
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	number unknown
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	number unknown
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	none
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	Number unknown
If yes, how many regular inspections have been conducted in 2008?	Number unknown
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	Number unknown
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	yes
If yes, how many?	10
If no, how are preparation processes inspected?	
Please, specify other authorisation	

GREECE	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
If yes, please describe	
If no, please specify why not	No system has been set up and no inspectors have been trained for that
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	

7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	other
Please, specify other authorisation	no answer
HUNGARY	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	The NPHMOS launched a so called “complex inspection” of health care providers, which contains the control of medical, hygienic and nursing conditions of health care. However parallel the ministerial decree on minimum requirements is under modification, and this process will involve the rules of tissues banks, therefore there was no inspection related to TE’s. At the end of 2008 there was conducted an inspection through regional offices

	of NPHMOS focuses on medical document, inner documents of quality measures, vocational processes and responsible persons of tissue and cell banks. This inspection was special, non-regular inspection by the regional authority of NPHMOS at 19 tissue and cell banks..
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other	

than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
IRELAND	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Full on-site inspections are performed following receipt of an application for tissue establishment authorisation. Following authorisation, routine inspections are performed on a 2-yearly basis or as required following notification of a SAR or SAE or following a major change to the Tissue Establishment or to the activites undertaken by the Tissue

	Establishment. (As per Directive 2004/23/EC Requirements)
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	2
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	8
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	0
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	1
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	0

7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	0
7.3.11 How many regular inspections of cord blood banks were conducted?	0
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	1 - Procurement Organisation
7.3.14 How many regular inspections of other tissue establishments were conducted?	0
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	2
If yes, how many regular inspections have been conducted in 2008?	0
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	0
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
ITALY	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	All tissue banks receive a full CNT site inspection on a 2 yearly cycle. Inspections of HPC centers have begun on 2007 and are performed by joint CNT/CNS teams. Other HPC centres are being given a provisional certification on the basis of a desk based review of compliance conducted jointly by CNT and CNS. For HPC centres that apply for a JACIE inspection, CNT/CNS inspectors participate in the inspection

If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	
Advanced therapies	Yes
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	1
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	16
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	1
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	5
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	1

7.3.11 How many regular inspections of cord blood banks were conducted?	1
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection; on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
LITHUANIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	If yes, please describe: State Health Care Accreditation Agency controls over compliance with licence conditions; State Medical Audit Inspectorate under the Ministry of Health of the Republic of Lithuania performs audit in the case of deficiencies. It controls over and assesses the quality of health care institution's (including TE) cervices; National Transplant Bureau is also responsible for control measures, but until recently it did not have resources for making inspections nor competent experienced inspectors.
If no, please specify why not	

7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	0
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	0
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	0
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	1
7.3.11 How many regular inspections of cord blood banks were	1

conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	0
7.3.14 How many regular inspections of other tissue establishments were conducted?	0
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
MALTA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
If yes, please describe	
If no, please specify why not	The Regulatory Division is in the phase of establishing capacity build up.
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	

Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	

7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
NETHERLANDS	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Health Care Inspectorate inspects once in 2 years on site
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	39
7.3.2 How many regular inspections of skin, musculo-skeletal,	0

opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	1
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	

If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
NORWAY	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
If yes, please describe	
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	

7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	other
Please, specify other authorisation	The inspections are the responsibility of another body - Norwegian Board of Helath. We can't answer these questions

POLAND	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Pre-Inspection Activities Inspection Methodology Opening Meeting Review of Documentation Site Inspection
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	4
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	10
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	0
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	0
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	0

7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	1
7.3.11 How many regular inspections of cord blood banks were conducted?	7
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	2
7.3.14 How many regular inspections of other tissue establishments were conducted?	0
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection; on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
PORTUGAL	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	All tissue establishments will be inspected, according with guidelines that are being prepared. Regarding reproductive cells, it is in the CNPMA' agenda to create and implement inspections and control measures for ART centres.
If no, please specify why not	

7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	Concerning reproductive cells there is no interaction or overlap
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were	

conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
ROMANIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Regular inspections every two years according to the Directive 2004/23/EC done by National Transplant Agency together with the Department of Control in Public Health – and initial inspections for accreditation done by the same institutions.
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	

Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	12
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	6
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	9
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	0
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	0
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	2
7.3.11 How many regular inspections of cord blood banks were conducted?	0
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	0
7.3.14 How many regular inspections of other tissue	2 Pancreatic Cells

establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection; on the basis of an assessment of a submitted dossier
Please, specify other authorisation	
SLOVAKIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Law 282/2006 Art.1/16 (3) b,c and (4) The inspection system is not functioning so far, as the designation of the official body which will provide inspections (in this case the State Institute for Drug Control, SUKL) needs to be designated by Law. This Law was not yet adopted by the Parliament)
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been	no

conducted in 2008?	
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no

If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	other
Please, specify other authorisation	It is not yet in place and will be provided together with the inspections
SLOVENIA	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	According to the 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/preauthorisation inspection and regular inspection must be performed each 2 years. There is also possibility for control measures.
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	Yes
Advanced therapies	Yes
Medical devices	No
Others	No
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	4
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	0

7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	1
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	0
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	0
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	1
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	0
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	1
7.3.11 How many regular inspections of cord blood banks were conducted?	0
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	1
7.3.14 How many regular inspections of other tissue establishments were conducted?	0
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	

If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
SPAIN	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
If yes, please describe	Centres authorised for Amnion are also included in the registe
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	

7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	other
Please, specify other authorisation	the questions from 7.2 to 7.5 where not answered
SWEDEN	

7.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
If yes, please describe	
If no, please specify why not	As for all supervision of health and medical care, including the area of blood, tissues and cells, inspectors for conducting audits are situated regionally. The organisational structures are in place and standards for supervision are to be designed during the spring and summer of 2009. These standards will not only be based on the EC-directives but also existing regulations for quality and patient's safety, which all supervision in Sweden is based on. Supervisions will begin during fall of 2009.
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	Yes
Pharmaceuticals	No
Advanced therapies	No
Medical devices	No
Others	No
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	

7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
TURKEY	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

If yes, please describe	Instruction 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)
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	no
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	
7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	

7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	
7.3.11 How many regular inspections of cord blood banks were conducted?	
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	
7.3.14 How many regular inspections of other tissue establishments were conducted?	
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted ?	
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	no
If yes, how many initial inspections have been conducted in 2008?	
If yes, how many regular inspections have been conducted in 2008?	
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	
UNITED KINGDOM	
7.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

If yes, please describe	All Phase 1 inspections (desk based evaluation) are conducted as and when applications or updated assessment information is submitted by TE. The HTA schedules Phase 2 inspections (site visit) on a quarterly basis while ensuring that all TE are inspected every 2 years as required by Directives 2004/23/EC, 2006/17/EC and 2006/86/EC. Within this model, TE are assigned an inspection date based on a risk rating used to inform the scheduling. Many factors make up the risk rating including: the perceived risk of non-compliance with relevant legislation, information brought to our attention through other sources (whistle-blowing), the Responsible Person not responding to our enquiries. The HTA utilises an escalating scale of control measures to ensure compliance with the Human Tissue (Quality and Safety for Human Application) Regulations. The scale includes; 1) advice and guidance 2) conditions 3) special directions 4) suspension 5) revocation
If no, please specify why not	
7.2 Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
If yes, please specify	
Blood	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Others	
Specify others	
7.3 Have any inspections of tissue establishments been conducted in 2008?	yes
7.3.1 How many inspections for initial accreditation of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	16
7.3.2 How many regular inspections of skin, musculo-skeletal, opthalmic, vascular tissue establishments were conducted?	31
7.3.3 How many inspections were conducted in skin, musculo-skeletal, opthalmic, vascular tissue establishments following serious adverse events or reactions, or suspicion thereof?	0
7.3.4 How many inspections for initial accreditation of assisted reproduction centres were conducted?	Not applicable
7.3.5 How many regular inspections in assisted reproduction centres were conducted?	Not applicable

7.3.6 How many inspections were conducted in assisted reproduction centres following serious adverse events or reactions, or suspicion thereof?	Not applicable
7.3.7 How many inspections for initial accreditation of HPC establishments (other than cord blood) were conducted?	12
7.3.8 How many regular inspections in HPC establishments (other than cord blood) were conducted?	11
7.3.9 How many inspections in HPC establishments (other than cord blood) following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.10 How many inspections for initial accreditation of cord blood banks were conducted?	8
7.3.11 How many regular inspections of cord blood banks were conducted?	4
7.3.12 How many inspections of cord blood banks following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.3.13 How many inspections for initial accreditation of other tissue establishments were conducted?	13 Chondrocytes (10), Stem cell lines (1), Cells for ATMP (1),Multi (1)
7.3.14 How many regular inspections of other tissue establishments were conducted?	10 Multi (6), Islets of Langerhans (1), Tissue for ATMP (3)
7.3.15 How many inspections of other tissues establishments following serious adverse events or reactions, or suspicion thereof were conducted?	0
7.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2008?	yes
If yes, how many initial inspections have been conducted in 2008?	39
If yes, how many regular inspections have been conducted in 2008?	0
If yes, how many inspections following serious adverse events or reactions, or suspicion thereof have been conducted in 2008?	0
7.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2008?	no
If yes, how many?	
If no, how are preparation processes inspected?	in the course of a general tissue establishment inspection
Please, specify other authorisation	

8. IMPORT/EXPORT (Article 9) Import/export refers to the exchange of tissue/cells with non EU27 Member States

AUSTRIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	

8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
BELGIUM	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Other methods
Please specify other methods	Fulfillment of Belgian law requirements and Belgian Superior Health Council standards.
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Other methods
Please specify other methods	Fulfillment of Belgian law requirements and Belgian Superior Health Council standards.
8.3.3 Ophthalmic (cornea, sclera, etc)	Other methods
Please specify other methods	Fulfillment of Belgian law requirements and Belgian Superior Health Council standards.
8.3.4 Vascular	Other methods
Please specify other methods	Fulfillment of Belgian law requirements and Belgian Superior Health Council standards.
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Other methods
Please specify other methods	Fulfillment of Belgian law requirements and Belgian Superior Health Council standards.
8.3.6 Cord blood	Other methods
Please specify other methods	Fulfillment of Belgian law requirements and Belgian Superior Health Council standards.
8.3.7 Reproductive cells (semen, egg cells)	Other methods
Please specify other methods	Fulfillment of Belgian law requirements
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	

EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
BULGARIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	Tissue bank Ost Development-France
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	Tissue bank “Osteocentre Bulgaria” Sofia (OCBG) Cytonet Sofia Tissue bank
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Other methods
Please specify other methods	Specific Ordinances (N:5/22.6.2004; N:13/15.4.2004) for import/export of tissues/cells.
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Other methods
Please specify other methods	Specific Ordinances (N:5/22.6.2004; N:13/15.4.2004) for import/export of tissues/cells.
8.3.3 Ophthalmic (cornea, sclera, etc)	Other methods
Please specify other methods	Specific Ordinances (N:5/22.6.2004; N:13/15.4.2004) for import/export of tissues/cells.
8.3.4 Vascular	Other methods
Please specify other methods	Specific Ordinances (N:5/22.6.2004; N:13/15.4.2004) for import/export of tissues/cells.
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Other methods
Please specify other methods	Specific Ordinances (N:5/22.6.2004; N:13/15.4.2004) for import/export of tissues/cells.
8.3.6 Cord blood	Other methods
Please specify other methods	Specific Ordinances (N:5/22.6.2004; N:13/15.4.2004) for import/export of tissues/cells.
8.3.7 Reproductive cells (semen, egg cells)	International references (e.g. ESHRE)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes

Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Country of origin Type of tissue/cell Units Germany HCS 1 Denmark Reproductive cells 134 USA Musculo-Skeletal 108
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	Tissue bank “Osteocentre Bulgaria” Sofia (OCBG)
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Country of destination Type of tissue/cell Units USA Musculo-Skeletal 6218
CROATIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Not applicable (no imports)
Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	

8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Sweden (EU Country) - Cornea - 3
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
CYPRUS	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements); International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements); International references (NETCORD/WMDA)
Please specify other methods	

8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements); International references (e.g. ESHRE)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
CZECH REPUBLIC	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)

Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	International references (e.g. ESHRE)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Japan Amnion membrane 4 pcs Lebanon Amnion membrane 6 pcs USA Ophtalmic (cornea) 176 pcs Afganistan Ophtalmic (cornea) 3 Argentina Ophtalmic (cornea) 10 Egypt Ophtalmic (cornea) 61 Georgia Ophtalmic (cornea) 17 Kingdom of Saudi Arabia Ophtalmic (cornea) 6 Syria Ophtalmic (cornea) 18 Turkey Ophtalmic (cornea) 8 United Arab Emirates Ophtalmic (cornea) 2
DENMARK	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	From the USA. (2 TE)
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	From the USA.
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)

Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Current data not yet available - HCS Current data not yet available - Reproductive cells Not applicable - Musculo-Skeletal
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Current data not yet available - HCS Current data not yet available - Reproductive cells - Musculo-Skeletal
ESTONIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	

8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA - 7 doses of sperm
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Cyprus- 7 embryos
FINLAND	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)

Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
FRANCE	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	It doesn't apply to gametes. Please find the list of suppliers from which the French tissue establishments import tissues : • Osteotech Inc.: 51 James Way, Eatontown, NJ 07724. Wright Medical Technologies (WMT°:5677 Airline Road, Arlington TN 38002
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	It doesn't apply to gametes. • The tissue establishment « Banque Française des yeux » (BFY) (in Paris), • Etablissement Français du Sang – Alpes-Méditerranée (in Marseille), The tissue establishment « OST-DEVELOPPEMENT » (in Clermont-Ferrand
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	

8.3.1 Skin	Other methods
Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in the french regulation. For reproductive cells there are equivalent standards (bilateral agreements).
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Other methods
Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in the french regulation.
8.3.3 Ophthalmic (cornea, sclera, etc)	Other methods
Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in the french regulation.
8.3.4 Vascular	Other methods
Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in french regulation.
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Other methods
Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in french regulation.
8.3.6 Cord blood	Other methods
Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in french regulation.
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements); Other methods

Please specify other methods	The tissue banks which want to import tissues or cells from third countries must be authorized to import these products by the French Health products and safety Agency. They must give to the Agency the proof that the tissus and celles they import have been procured and collected according safety and quality santards equivalent to the requirements mentionned in french regulation.
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Afssaps delivers authorisations for HCS (peripheral blood stem cells- cord blood unit - lymphocytes). Due to the emergency they are nominative.(Austria :35;Canada :1- Israel:6;Norway :1;Taiwan :2- USA :193)
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	Here after, the list of French tissue establishments which are authorised to perform exportation of tissues to 3rd countries outside the EU: - The company « BIOBANK » : Z. A. Lavoisier, 4 rue Lebon - 77220 Presles En Brie, - Tissue Bank of France (TBF) - GENIE TISSULAIRE: 6 rue d'Italie - 69780 Lyon-Mions, - The company "OST DEVELOPPEMENT" (OCE) : 15 rue George Besse - 63017 Clermont-Ferrand Cedex 2, - The association « OSTEOBANQUE D'AUVERGNE » (OBA) : 2 rue Flameng Carrefour Montalembert - 63000 Clermont-Ferrand, Etablissement Français du Sang – Bourgogne Franche Comté : 1, boulevard A. Fleming, BP 1937 - 25020 Besançon. Hospices civils de Lyon We don't have such a list for reproductive cells. It would not be relevant for ART sector.
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	The cells exported are HCS (peripheral blood stem cells- cord blood unit - lymphocytes):Australia :5 ; South Africa :1 ; Brazil :3 ;Canada :6; Chili :1; Israel :7 ;Russia :1 ;Uruguay :1 ;USA: 38)
GERMANY	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	Responsibility of the competent authorities of the german federal Laender
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	see above 8.1

8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.4 Vascular	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	International references (e.g. ESHRE)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Not specified HCS (PBSC+CBSC) 67+0
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	in 2007
GREECE	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	Usually tissues are imported from USA
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No

Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Other methods
Please specify other methods	Certificate of compliance to EU directives
8.3.3 Ophthalmic (cornea, sclera, etc)	Other methods
Please specify other methods	Certificate of compliance to EU directives
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA, Israel, Singapore - HSC + Cord blood - 18+1+1
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
HUNGARY	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	Only internal register.

8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	Only internal register.
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
IRELAND	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No

Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	This information is captured on the Tissue Establishment Authorisation issued to each Tissue Establishment. Also each Tissue Establishment is required to submit information on import / export activites on the Annual Report that is submitted to the Irish Medicines Board.
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements); International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements); International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Information is not yet available for 2008. This information will be submitted by Tissue Establishments in the Annual Report to the Irish Medicines Board which is required mid year.
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	This information is captured on the Tissue Establishment Authorisation issued to each Tissue Establishment. Also each Tissue Establishment is required to submit information on import / export activites on the Annual Report that is submitted to the Irish Medicines Board.

8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Information is not yet available for 2008. This information will be submitted by Tissue Establishments in the Annual Report to the Irish Medicines Board which is required mid year.
ITALY	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	BMDW for HPC
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	only for muscolo-skeletal banks (tissues) BMDW for HPC
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements); International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	HSC USA 124 SWISS 2 CANADA 5 ISRAEL 8 AUSTRALIA 2 TAIWAN 1 MUSCOLO SKELETAL USA 1365
EXPORTS	

8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	BMDW FOR HPC
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	HSC USA 16 SWISS 3 AUSTRALIA 3 RUSSIA 1 ARGENTINA 1 TURCHIA 1 MUSCOLO SKELETAL SWISS 1 CORNEA BOLIVIA 7 ARABIA SAUDITA (Jeddah) 12 ARABIA SAUDITA (Riad) 28 COSTA D'AVORIO (Abidjan) 2 EMIRATI ARABI UNITI (Abu Dhabi) 3 GEORGIA (Tbilisi) 33 KENIA (North Kinangop) 2 SERBIA (Belgrado) 15 SUDAFRICA (Pretoria) 25 SVIZZERA (Binningen) 6 SVIZZERA (Liestal) 1 SVIZZERA (Lucerna) 22 SUDAFRICA (Pretoria) 1 SVIZZERA (Binningen) 3 ARABIA SAUDITA (Jeddah) 15 SUDAFRICA (Pretoria) 50 SVIZZERA (Lucerna) 1
LITHUANIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)
Please specify other methods	

8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	Country of origin Type of tissue/cell Units Israel -HCS -1 -Reproductive cells- -Musculo-Skeletal-
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
MALTA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Not applicable (no imports)
Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)

Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
NETHERLANDS	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	

8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
NORWAY	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	Part of the register on licenced tissue establishments
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)

Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA HCS 3 units
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	As for import
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
POLAND	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	

8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Not applicable (no imports)
Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
PORTUGAL	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements); International references (e.g. EATB, AATB)

Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements); International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements); International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	US. The answer is NO for reproductive cells. The answers to the questions 8.3.1 - 8.3.7 is Not applicable for reproductive cells.
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	HSC. The answer is NO for reproductive cells
ROMANIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes
Yes, please specify	All the imports of tissues and cells are done only with a special authorization issued by the National Transplant Agency. The imports are allowed only from tissue establishments agreed by the National Transplant Agency, after checking the standards of those tissue establishments.
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Other methods
Please specify other methods	The standards and criteria stipulated by the EU Directives 2004/23/EC, 2006/17/EC,

	2006/86/EC
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Other methods
Please specify other methods	The standards stipulated by the EU Directives 2004/23/EC, 2006/17/EC, 2006/86/EC
8.3.3 Ophthalmic (cornea, sclera, etc)	Other methods
Please specify other methods	The standards stipulated by the EU Directives 2004/23/EC, 2006/17/EC, 2006/86/EC
8.3.4 Vascular	Other methods
Please specify other methods	The standards stipulated by the EU Directives 2004/23/EC, 2006/17/EC, 2006/86/EC
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Other methods
Please specify other methods	The standards stipulated by the EU Directives 2004/23/EC, 2006/17/EC, 2006/86/EC
8.3.6 Cord blood	Other methods
Please specify other methods	The standards stipulated by the EU Directives 2004/23/EC, 2006/17/EC, 2006/86/EC
8.3.7 Reproductive cells (semen, egg cells)	Other methods
Please specify other methods	The standards stipulated by the EU Directives 2004/23/EC, 2006/17/EC, 2006/86/EC
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA - Musculo-Skeletal - 38 USA - Skin - 4
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA - HCS – cord blood - 1
SLOVAKIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	

8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	3 eye banks
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
SLOVENIA	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	1 TE authorised in 2008 has also authorisation for export/import

8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Not applicable (no imports)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	Not applicable (no imports)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA: 1 HSC
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	1 TE authorised in 2008 has also authorisation for export/import
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
SPAIN	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No

Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Other methods
Please specify other methods	We only import HSC and cord blood. All HSC and cord blood have the requirements of international standard (JACIE/WMDA)
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Not applicable (no imports)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA); Not applicable (no imports)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA - HCS - 112 Australia - HCS - 13 Israel - HCS - 1 Switzerland - HCS - 1 Taiwan - HCS - 1
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	USA - HCS - 51 Jordania - HCS - 4 Colombia - HCS - 3 Mexico - HCS - 3 Canada - HCS - 2 Switzerland - HCS - 2 Otros - HCS - 5 Ecuador - Musculo-Skeletal - 3 Andorra - Musculo-Skeletal - 3
SWEDEN	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	No
Yes, please specify	

8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	No
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.4 Vascular	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.6 Cord blood	Equivalent standards (bilateral agreements)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Equivalent standards (bilateral agreements)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	No
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
TURKEY	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to your country?	Yes

Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Not applicable (no imports)
Please specify other methods	
8.3.3 Ophthalmic (cornea, sclera, etc)	International references (e.g. EATB, AATB)
Please specify other methods	
8.3.4 Vascular	Not applicable (no imports)
Please specify other methods	
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	International references (JACIE/WMDA)
Please specify other methods	
8.3.6 Cord blood	International references (NETCORD/WMDA)
Please specify other methods	
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	No
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	
UNITED KINGDOM	
IMPORTS	
8.1 Do you have a register of third countries tissue establishments from which do you import tissues and cells to	No

your country?	
Yes, please specify	
8.2 Do you have a list/register of authorised tissue establishment that are explicitly authorised to perform importation of tissues and cells from third countries outside th EU?	Yes
Yes, please specify	We maintain a register of all establishments and the range of activities they are licensed for including importation.
8.3 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of tissues and cells from third countries?	
8.3.1 Skin	Other methods
Please specify other methods	Quality and safety standards for importation of tissues and cells are verified initially during the Phase 1 inspection (desk based evaluation). A further review is carried out during the Phase 2 inspection (site visit) by reviewing appropriate documents including, contracts and SOPs.
8.3.2 Musculo-Skeletal (bone, tendons, fascia, etc)	Other methods
Please specify other methods	Quality and safety standards for importation of tissues and cells are verified initially during the Phase 1 inspection (desk based evaluation). A further review is carried out during the Phase 2 inspection (site visit) by reviewing appropriate documents including, contracts and SOPs.
8.3.3 Ophthalmic (cornea, sclera, etc)	Other methods
Please specify other methods	Quality and safety standards for importation of tissues and cells are verified initially during the Phase 1 inspection (desk based evaluation). A further review is carried out during the Phase 2 inspection (site visit) by reviewing appropriate documents including, contracts and SOPs.
8.3.4 Vascular	Other methods
Please specify other methods	Quality and safety standards for importation of tissues and cells are verified initially during the Phase 1 inspection (desk based evaluation). A further review is carried out during the Phase 2 inspection (site visit) by reviewing appropriate documents including, contracts and SOPs.
8.3.5 Haematopoietic Stem cells (HSC) (other than cord blood)	Other methods
Please specify other methods	Quality and safety standards for importation of tissues and cells are verified initially during the Phase 1 inspection (desk based evaluation). A further review is carried out during the Phase 2 inspection (site visit) by reviewing appropriate documents including, contracts and SOPs.
8.3.6 Cord blood	Other methods

Please specify other methods	Quality and safety standards for importation of tissues and cells are verified initially during the Phase 1 inspection (desk based evaluation). A further review is carried out during the Phase 2 inspection (site visit) by reviewing appropriate documents including, contracts and SOPs.
8.3.7 Reproductive cells (semen, egg cells)	Not applicable (no imports)
Please specify other methods	
8.4 Did you import tissues/cells from 3rd countries during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	As a CA, we license establishments that import tissues/cells from 3rd countries. We do not undertake this activity. We require licensed establishments to report on the quantities/volumes imported. Establishments are not currently required to identify to the HTA, the country of origin of imported tissues and / or cells. Type of tissue/cell HCS units 436 Type of tissue/cell musculo-skeletal units 888
EXPORTS	
8.5 Do you have a list/register of tissue establishment that are explicitly authorised to perform exportation of tissues and cells to third countries outside the EU?	Yes
Yes, please specify	We maintain a register of all establishments and the range of activities they are licensed for; including export.
8.6 Did you export tissues/cells during 2008?	Yes
Yes, please provide us with the data concerning the importing quantities/volume of tissues and cells by Country of origin	As a designated CA under 2004/23/EC we license establishments that export tissues/cells from 3rd countries. We do not undertake this activity. We require licensed establishments to report on the quantities/volumes exported. Type of tissue/cell HCS units 109 Type of tissue/cell musculo-skeletal units 0

9. INTRA COMMUNITY EXCHANGES

AUSTRIA	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
BELGIUM	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	The dead line for submitting the annual reports for 2008 by the tissue establishments is April 30 2009. These data will be provided by half May.
BULGARIA	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
CROATIA	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
CYPRUS	
9.1 Do you have intra-community exchanges of tissues and cells?	No

9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
CZECH REPUBLIC	
9.1 Do you have intra-community exchanges of tissues and cells?	
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
DENMARK	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	We have had no experience of sanctions or refusals by other countries with higher standards than that applied by Denmark.
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Current data not yet available
ESTONIA	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	The quality measures are determined by mutual agreement between establishments.
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Haematopoietic Stem Cells Country of origin Germany 6 doses Finland 2 doses
FINLAND	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
FRANCE	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes

9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Member State of destination Type of tissue/cell Units Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Netherland, Spain, Sweden, Switzerland, UK PBSC:31 CBU:37 Lymphocytes:5 Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Netherland, Spain, Sweden, Switzerland, UK PBSC:286 CBU:108 Lymphocytes:27 Member State of origin Type of tissue/cell Units Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Netherland, Spain, Sweden, Switzerland, UK PBSC:286 CBU:108 Lymphocytes:27
GERMANY	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
GREECE	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	no data available about the amount or country of exchange
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Germany, Cyprus, Italy, Spain, UK, France - HSC + Cord blood - 46
HUNGARY	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
IRELAND	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	Each Tissue Establishment must implement a Service Level Agreement with the Tissue Establishments to whom they distribute to in the EEA. The receiving Tissue Establishment in the Member State of destination is responsible for ensuring that the tissues and cells received meet the requirements of the EU Directive and any addition national requirements.

9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Information is not yet available for 2008. This information will be submitted by Tissue Establishments in the Annual Report to the Irish Medicines Board which is required mid year.
ITALY	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	For HPC there are the same quality measures because we used the international standard (WMDA/JACIE)
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	HSC Germany 16 France 13 Spain 2 United Kingdom 3 Polonia 3 Grecia 2 Austria 2 Svezia 1 Olanda 2 Rep. Ceca 1 Ungheria 1 Portugal 1 Slovenia 1 CORNEA BELGIO (Anversa) 1 GERMANIA (Ahaus) 42 GERMANIA (Berlino) 5 GERMANIA (Colonia) 16 OLANDA (Amsterdam) 2 OLANDA (Maastricht) 1 OLANDA (Nijmegen) 1 OLANDA (Rotterdam) 3 REGNO UNITO (Londra) 8 SPAGNA (Barcelona) 34 BOLIVIA (Santa Cruz) 2 SUDAFRICA (Pretoria) 1 SVIZZERA (Binningen) 3 GRECIA (Atene) 1 HSC Germany 200 France 11 Spain 2 United Kingdom 14 Polonia 2 Rep. Ceca 6 Portugal 3 Cipro 1 Danimarca 1 Slovenia 1 Muscolo-skeletal Belgio 5 Other UE country 12 CORNEA Olanda 34
LITHUANIA	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	we follow ourselves EU requirements and assume that other EU countries with which we do exchange do the same
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Germany HPC 36- Poland HPC 2 -Czech Republic HPC 1
MALTA	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
NETHERLANDS	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	It is the responsibility of individual tissue establishment
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	

NORWAY	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	The exchange should be covered by an agreement. In the agreement Norwegian demands are specified
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Semen is exchanged into Norway from Denmark. Number of units unknown
POLAND	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	there are simillar quality measures
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Germany, Poland, heart valves, 20
PORTUGAL	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	The answer is NO for reproductive cells
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
ROMANIA	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	We apply the quality measures stipulated by the EU Directives.
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Denmark - Reproductive cells (sperm) - 289
SLOVAKIA	
9.1 Do you have intra-community exchanges of tissues and cells?	No
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
SLOVENIA	

9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	Tissue establishment obtain information about more stringent quality measures established by other Member States.
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	Country of destination: Slovenia Country of origin: Germany, Italy, Great Britain Type of tissue/cell: HSC Number of units: 8
SPAIN	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	France HSC 39 UK HSC 16 Italy HSC 14 Germany HSC 6 Others HSC 11 Greece Musculo-Skeletal 20 Portugal Musculo-Skeletal 57 Germany Vessels and valves 39 The Nederland Vessels and valves 9 Others Vessels and valves 15 Germany HSC 77 France HSC 19 UK HSC 10 Others HSC 16
SWEDEN	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	Authorisation process is not completed. As for all exchange agreements are requested.
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
TURKEY	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	
UNITED KINGDOM	
9.1 Do you have intra-community exchanges of tissues and cells?	Yes
9.2 If yes, how do you address the possible more stringent quality measures established by other Member States? Please specify	All tissue and cells that enter the UK for patient use must meet the requirements set out by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Directions given under the Human Tissue Act 2004.
9.3 If data available, please provide us with the following data concerning exchanges during 2008: country of destination, country of origin, type of tissue/cell, number of units	

10. SERIOUS ADVERSE EVENTS AND REACTIONS (Artile 11)

AUSTRIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	We have built our vigilance systems on the roots of the haemovigilance system. Moreover we are taking part at the Eustite vigilance arm. At the moment we have established 2 vigilance-forms for TE to inform the CA. Risk based approach to verify the need of national warnings
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	all events that affect the quality of tissue and cells
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	all reactions that could induce reactions in other recipients, all reactions that interfere the human health
BELGIUM	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	Standard notification forms (electronic transmission) and instructions for reporting to the biovigilance centre of the Federal Agency 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.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes

If yes, please give a short description of the system	• The application of a tissue or cells that did not fulfil the safety and quality requirements. • A near miss: the distribution of a tissue or cells that did not fulfil 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 fulfil 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.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If 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 complications in donors related to the preparation of the donor and the collection procedure.
BULGARIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	The system is described in details in specific ordinance for SAE&SAR (Ordinance N:10/30.3.2007).
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Only definitions from Organ, tissue and cell act but not specific criteria.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Only definitions from Organ, tissue and cell act but not specific criteria.
CROATIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	Croatia is taking part in the Vigilance and Surveillance Pilot Project on Reporting of Serious Adverse Reactions and Serious Adverse Events. Reporting system is organised through the same National organ coordination network and is partially in place (as pilot project).
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes

If yes, please describe the criteria	Definitions are: Serious Adverse Event: any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that mind 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. SAR and SAE are reported in accordance to the tolls and methodology of Vigilance and Surveillance Pilot project on Reporting of Serious Adverse Reactions and Serious Adverse Events (EUSTITE)
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Definitions are: Serious Adverse Reaction: 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. SAR and SAE are reported in accordance to the tolls and methodology of Vigilance and Surveillance Pilot project on Reporting of Serious Adverse Reactions and Serious Adverse Events (EUSTITE)
CYPRUS	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	Specimen Forms supplied to TEs and are obliged by legislation to report serious adverse events
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Compromising the safety of tissues and compromising the health of the recipient
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Compromising the safety of tissues and compromising the health of the recipient
CZECH REPUBLIC	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes

If yes, please give a short description of the system	- Immediate notification to the tissue establishment responsible for the release of respective tissues and cells - Immediate notification to the State Institute for Drug Control - Analyses and corrective measures are ensured by releasing tissue establishment in cooperation with all relevant participants - Report on analyses and corrective measures is submitted to the State Institute for Drug Control - Annual summary and report by the State Institute for Drug Control.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Stated by definition (identical with definition of directive 2004/23/EC art. 3 letter m), and n); reporting format according to directive 2006/86/EC).
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Stated by definition (identical with definition of directive 2004/23/EC art. 3 letter m), and n); reporting format according to directive 2006/86/EC).
DENMARK	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	The National systems and practices for the reporting of serious adverse events/incidents were communicated via our website to all tissue establishments. The reporting system is presented as an on-line electronic scheme for tissue establishments, or users, to notify our offices of any serious adverse reaction or serious adverse event in the use of human tissues or cells. The initial reporting information, and the conclusion reports, follow the structure and format of the European Directives.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Clearly stated at the Agency website, as specified in the Directive.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	As specified by the Directive, except for art SECTOR.
ESTONIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes

If yes, please give a short description of the system	Tissue establishments have to establish by regulation biovigilance system of reporting adverse events and adverse reactions to the CA. Responsible person of establishment is liable of reporting and investigation of adverse events. Exchange of information between tissue establishments and hospitals are foreseen in bilateral agreements.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Serious is defined as any adverse event 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;
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Serious is defined as any unintended response or untoward occurrence of the transmission of a communicable disease, or a event that may cause life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;
FINLAND	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	The system for reporting serious adverse events and reactions is described in the Decree 1302/2007 given by the Ministry of Social Affairs and Health. The forms for reporting are as annexes of the Decree (comliant with Directive 2006/86/EC).
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	We utilize Eustite document: "Tools for Vigilance and Surveillance of Human Tissues and Cells" providing definition and classification of adverse events and reactions.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	We utilize Eustite document: "Tools for Vigilance and Surveillance of Human Tissues and Cells" providing definition and classification of adverse events and reactions.
FRANCE	

10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	1) In tissues and cells field At the top of the system there is 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. 2) In reproductive field It is managed by ABM as the competent authority. There is a designated local ART vigilant person in each centre.The cooperation between competent authorities is important, especially with Afssaps for medical devices vigilance or biovigilance
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Adverse events are defined as failure from an element at one step of the process (procurement, testing processing, preservation, storage...) that can entail an adverse reaction for the living donor or for the patient (Examples : microbiological contamination, incomplete serological data) The are some specific definitions of what has to be declared in ART field.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Serious adverse events are defined as events that happen with abnormal frequency and than could lead to serious adverse reactions for one or several living donors and/or one or several recipients (Examples : failure of the traceability, failure of viral inactivation process or repetition of an event) In reproductive field, a serious adverse event is defined as follows : any adverse event which could lead to serious adverse reactions. Any adverse event which could lead to an error in attribution or a loss of gametes, germinal tissues or embryos with a loss of procreation chance should also be considered as a serious adverse event. A serious adverse reaction is defined as follows : any adverse reaction that could lead to the death, or to a life-threatening event, or to result in an hospitalisation, a prolongation of hospitalisation or of any other illness, or that may occur in one or more donors or people who are involved in ART.
GERMANY	
10.1 Do you have a system in place for the reporting of serious	Yes

adverse events and reactions (Article 11(1))?	
If yes, please give a short description of the system	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.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If 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
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
GREECE	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	No
If yes, please give a short description of the system	
If no, why not	Specific legislation pending
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
HUNGARY	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	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
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as	Yes

"serious")?	
If 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.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If 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.
IRELAND	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	An on-line reporting system is available on the website of the Irish Medicines Board for the reporting of Serious Adverse Reactions and Events. Submitted reports are analysed by the Vigilance Department of the Irish Medicines Board and follow up information is requested if required.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	SAEs are reported as per Directive 2004/23/EC and 2006/86/EC requirements. However, all Tissue Establishments are encouraged to report all adverse events and the Irish Medicines Board will then decide if the criteria are fullfilled and if further information is required. The IMB also participates in the EUSTITE Vigilance and Surveillance Tools Pilot.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	SARs are reported as per Directive 2004/23/EC and 2006/86/EC requirements. However, all Tissue Establishments are encouraged to report all adverse reactions and the Irish Medicines Board will then decide if the criteria are fullfilled and if further information is required. The IMB also participates in the EUSTITE Vigilance and Surveillance Tools Pilot.
ITALY	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes

If yes, please give a short description of the system	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. CNS: The Clinical Unit, which utilizes tissues or cells, must notify every serious adverse event to the tissue establishment. The tissue establishment responsible person (article 17) has to notify to the Regional CA and to the National CAs (National Blood Centre and National Transplant Centre).
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	We are testing the use of the EUSTITE criteria
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	We are testing the use of the EUSTITE criteria
LITHUANIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	The system is based on the immediate paper reports
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	The description goes exactly along with Directive and along the LAW ON DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS, by the order of the Minister of Health of the Republic of Lithuania on 19 November 1996 No I-1626 (As last amended on 19 October 2006 - No X-867)
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	The description goes exactly along with Directive and along the LAW ON DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS, by the order of the Minister of Health of the Republic of Lithuania on 19 November 1996 No I-1626

	(As last amended on 19 October 2006 - No X-867)
MALTA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	Tissue and cell establishments and end users encountering serious adverse reactions and events should report these to a National Biovigilance Unit within the Department of Health Care Services Standards, within the Directorate General for Public Health Regulation (the Competent Authority). In addition, reports on the outcome of investigations of serious adverse reactions and events are also reported through the same system. http://www.sahha.gov.mt/pages.aspx?page=1228
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	The criteria are those suggested in the EUSTITE Vigilance Tools - users are referred to this tool.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	The criteria are those suggested in the EUSTITE Vigilance Tools - users are referred to this tool.
NETHERLANDS	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	Via TRIP and Inspectorate (IGZ)
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
NORWAY	

10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	No
If yes, please give a short description of the system	
If no, why not	Under establishment
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
POLAND	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	- for tissues and somatic cells by National Center of Tissue and Cell Banking - for stem cells (blood marrow, circulating blood) by Poltransplant There are forms for rapid notification and conclusions of of serious adverse events and reactions.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
PORTUGAL	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	To report SAE2007, a national inquire has been distributed on 2008 to all tissue establishments (except for reproductive cells) A National inquire about SAE 2008 is on going. A national electronic registry is under development. The answer is NO for reproductive cells
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes

If yes, please describe the criteria	The definitions included in the law 1272009, are those included in the Directives. Since January 2009, five different expert's working groups are preparing a document that includes definitions and specific guidelines on SAE and SAR. The work should be concluded by the end of June 2009. The answer is NO for reproductive cells.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	The definitions included in the law 1272009, are those included in the Directives. Since January 2009, five different expert's working groups are preparing a document that includes definitions and specific guidelines on SAE and SAR. The work should be concluded by the end of June 2009. The answer is NO for reproductive cells.
ROMANIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	Transposition of the Directive 2006/86/EC – Minister of public Health's Order no 1763/2007 – Annex – Art. 9
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Definiton of "serious adverse events" and serious adverse reactions according to the Directive 2004/23/EC – Art. 3 – transposed in the Minister's of Public Health Order no. 1242/2007 – Annex – Art. 1
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Definiton of "serious adverse events" and serious adverse reactions according to the Directive 2004/23/EC – Art. 3 – transposed in the Minister's of Public Health Order no. 1242/2007 – Annex – Art. 1
SLOVAKIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	SAEs and SARs have to be reported to the CA. The reporting obligations and reporting forms are contained and published in Governmental Decree 622/2007, §4
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes

If yes, please describe the criteria	(5) Závažná nežiaduca udalosť je akýkoľvek negatívny jav súvisiaci s odberom, testovaním, spracovaním, skladovaním a distribúciou tkanív a buniek, ktorý by mohol viesť k prenosu infekčnej choroby, k úmrtiu alebo ktorý ohrozuje život, predlžuje hospitalizáciu a chorobnosť alebo spôsobuje invaliditu podľa osobitného predpisu.52b)
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	6) Závažná nežiaduca reakcia je nezamýšľaná odozva vrátane infekčnej choroby u darcu alebo u príjemcu súvisiaca s odberom orgánov, tkanív alebo buniek alebo s ich humánnym použitím, ktorá spôsobuje smrť, ohrozuje život, vyvoláva zdravotné postihnutie, predlžuje hospitalizáciu a chorobnosť alebo spôsobuje invaliditu podľa osobitného predpisu.(52b)
SLOVENIA	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	According to the Rules on histovigilance (OG RS, No. 70/2008) Tissue establishment have to report SAE/R to the Slovenija transplant, which is responsible to report to the JAZMP. Human recipient or donor could report to medical doctor or directly to Slovenija transplant or JAZMP. Medical doctors are responsible to report to tissue establishment.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If 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 event or serious adverse reaction is the same as in Directive 2004/23/EC.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If 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 event or serious adverse reaction is the same as in Directive 2004/23/EC.
SPAIN	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes

If yes, please give a short description of the system	According to the RD 1301/2006 Spain a system for reporting SAE and reactions in place. They have to be reported to the appropriate level of the biovigilance network and a final form after the appropriate research must be sent. Potentially harmful cells or tissues are located and recipients at risk searched for, assessed and treated as needed. A final national report is to be carried out, and sent back to all the levels of the network.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Criteria of distribution (when a batch has been sent to the next step, i.e. an adverse event happened at the procurement facility and detected by the TE) Criteria of seriousness (any event or reaction that might lead to the transmission of a disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity)
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	Criteria of distribution (when a batch has been sent to the next step, i.e. an adverse event happened at the procurement facility and detected by the TE) Criteria of seriousness (any event or reaction that might lead to the transmission of a disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity)
SWEDEN	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	The reporting system for tissues and cells will be the same as the reporting system now being used within the area of blood Tissue establishments report adverse events and reactions in connection to the event/reaction and after investigation took place. Depending on the adverse event or reaction reported the deficiency is either closed, further questions are asked or actions are taken. Reported adverse events and reactions will be our register in conjunction to reporting tissue establishment.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	"Serious adverse event" and "serious adverse reaction" have the same definitions in the Swedish law as stated in art. 3 dir. 2004/23/EC.

10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	"Serious adverse event" and "serious adverse reaction" have the same definitions in the Swedish law as stated in art. 3 dir. 2004/23/EC.
TURKEY	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	No
If yes, please give a short description of the system	
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	No
If yes, please describe the criteria	
UNITED KINGDOM	
10.1 Do you have a system in place for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
If yes, please give a short description of the system	In line with the requirements of the EUTCD 2004/23/EC, 2006/17/EC and 2006/86/EC we require that notification of a suspected or actual serious adverse event/reaction is submitted by the establishment which is then followed up by the submission of a report once local investigations have taken place. The notification steps include an online reporting system, accessed on the HTA main webpage via a password entry, which includes 4 sections to be completed. - 1) organisation details, 2) relevant details, 3) event details and 4) summary and confirmation Definitions are provided on the webpage to explain the terms and a contact name is provided if the Responsible Person requires further assistance. The HTA is participating in the EUSTITE vigilance and surveillance pilot project created to record and monitor serious adverse events and reactions.
If no, why not	
10.2 Have you defined criteria for the reporting of serious adverse events to the competent authority (i.e. what is defined as "serious")?	Yes

If yes, please describe the criteria	The HTA definitions of serious adverse events are taken from the definitions set out in the EUTCD and are as follows: Serious Adverse Event (SAE) 'serious adverse event' means 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.
10.3 Have you defined criteria for the reporting of serious adverse reactions to the competent authority (i.e. what is defined as "serious")?	Yes
If yes, please describe the criteria	The HTA definitions of serious adverse reactions are taken from the definitions set out in the EUTCD and are as follows: Serious Adverse Reaction (SAR) 'serious adverse reaction' means 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.

11. VOLUNTARY UNPAID DONATION (Article 12)

AUSTRIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	In Austria everybody is a potential organ and tissue donor. There are no promotions in place
BELGIUM	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Law of December 19 2008 concerning the procurement and the use of human body material for medical use on humans or for scientific research: article 6: Not any profit may be offered in exchange of the donation of human body material. The donor may receive a compensation for costs or loss of income, that are a direct consequence of the donation. The King may fix more detailed rules for the implementation of the latter. The same rules have been laid down in the law of June 13 1986 concerning the removal and transplantation of organs (applies also on tissues and cells).
BULGARIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Art.5 and 6 from Organ, tissue and cell transplantation act. “Article 5. Human organs, tissues and cells may not be subject to an onerous transaction.” “Article 6. Advertising the availability of organs, tissues and cells with a view to seeking financial gain, as well as the offering of financial gain with a view to providing organs, tissues and cells, is prohibited.”
CROATIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	- The principle of Voluntary Unpaid donation is defined by law (Act on transplantation) - Each year MHSW prepare the national campaign promoting (voluntary unpaid) donation of organs and tissues and cells and celebration of National donation and transplantation day (26. may) - European donation and transplantation day
CYPRUS	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	In the Law 187(1)/007 is stated that tissue donation is voluntary unpaid and it is illegal to buy/sell tissues
CZECH REPUBLIC	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Donation of human tissues and cells is regulated by law. Only unpaid donation is possible.
DENMARK	

11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	This is specified in the national legislation from THE board of health .
ESTONIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	The principle of voluntary donation are fixed in law. Promotion of voluntary donation has been done by ministry, patient organisations and hospitals. Penalties to people violating the law have been established.
FINLAND	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	The priciple of Voluntary unpaid donations is regulated by law in Finland: Act on the Medical Use of Human Organs, Tissues and Cells (101/2001, revised 547/2007)
FRANCE	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	The principle of voluntary unpaid donation is mandatory in France is specified in the article L.1211-4of the french public health code.
GERMANY	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	
GREECE	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	L 2737/1999 published in A174/1999 Government Paper
HUNGARY	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	According to the Act on health care (CLIV/1997) 207. § - Donation of tissues can happen only without offset. The organization of social security gives allowances for donor only related to income loss and travel expenses, or in certain cases verifiable costs of medical or technical services for the donor.
IRELAND	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	It is the responsibility of each Tissue Establishment to implement the principle of voluntary unpaid donations.
ITALY	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	For organs, tissues and cells Law 91/99. National campaign are organised every year to promote donation For blood and HSC Law 219/2005.

LITHUANIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	as it is described in Directive's Article 12 and transposed to the LAW ON DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS, by the order of the Minister of Health of the Republic of Lithuania on 19 November 1996 No I-1626 (As last amended on 19 October 2006 - X-867) , Chapter IV, Article 11: CHAPTER IV PROHIBITION OF COMMERCIAL TRANSACTIONS Article 11. Impermissibility of Commercial Transactions 1. Tissues, cells and organs of a dead or living person cannot be the subject of civil commercial transactions. It shall also be prohibited to publish information about the need for human tissues, cells and organs or their availability seeking for financial or similar benefit. The Government or an institution authorised by it shall establish the procedure for import of tissues, cells and organs for transplantation into the Republic of Lithuania and that for their export from the Republic of Lithuania. 2. The expenses of healthcare institutions related to the removal, preparation and transportation of human tissues, cells and organs shall be reimbursed from the budget of the Compulsory Health Insurance Fund or from the state budget in accordance with the procedure prescribed by legal acts. The expenses related to the preparation and transportation of human tissues, cells and organs for transplantation when they are imported into or exported from the Republic of Lithuania shall be reimbursed in accordance with the procedure established by the Ministry of Health. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=230615 http://www.transplantacija.lt/content/teisesaktai.en.html
MALTA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	The Tissues and Cells (Quality and Safety) (LN271/06)> http://www.doi.gov.mt/EN/legalnotices/2006/11/LN271.pdf Regulation 9 (g) 9. (1) An establishment shall, in relation to the procurement of human tissues or cells: (g) encourage voluntary and unpaid tissue and cell donations with a view to ensuring that tissues and cells are, in so far as possible, provided from such donations
NETHERLANDS	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	
NORWAY	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Forskrift 7. mars 2008 om krav til kvalitet og sikkerhet ved håndtering av humane celler og vev § 14
POLAND	

11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	The principles of voluntary and unpaid donations are described in the cell, tissue and organ recovery, storage and transplantation act of July 1st, 2005. It is stated in its article 3 that It is not allowed to demand or accept payments or other financial benefit for cells, tissues and organs taken from donors. According to article 43 all those who disseminate notices about payable sales, purchases of cells, tissues and organs or about an agency for payable sales or purchases of cells, tissues and organs with the aim of transplanting them shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of up to one year. Article 44.1 says that all those who with the purpose of acquiring financial benefits buy or sell other people's cells, tissues or organs, run an agency for the purchase and sale of cells, tissues or organs or take part in transplantations of recovered in defiance of the regulations of the present act cells, tissues or organs that originate from living donors or human dead bodies, shall be liable to a penalty of imprisonment of up to three years.
PORTUGAL	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	As regards to reproductive cells, centres authorised to administer assisted reproduction techniques shall not assign any value to the genetic material donated or to embryos donated when calculating the fees payable (Article 17, Law 32/2006 of 26 July). In addition, purchase and sale of human eggs, semen or embryos or other biological material deriving from application of assisted reproduction techniques is hereby prohibited (Article 18, Law 32/2006 of 26 July). Nevertheless, the Law 12/2009 states that the donor can be reimbursed strictly based on the expenses associated with the donation (Article 22, Law 12/2009 of 26 March). Concerning the remaining tissues and cells the same law (Law 12/2009 (Article 22, Law 12/2009 of 26 March) is applied.
ROMANIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Law no. 95/2006 – Title VI– Art. 144, Art. 157, Minister's of Public Health Order no. 1242/2007.
SLOVAKIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	It is defined in the Law 282/2006 Art.1. (11)
SLOVENIA	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Maintenance of unpaid donation is determined by above mentioned acts. According to Rules on donating and production of human tissues and cells (OG RS, No. 70/2008) donors sign inform consent, which include statement about voluntary unpaid donation. For deceased donors the possibility for donation is communicated with relatives. Information about voluntary unpaid donation is also available in booklets, issued by Slovenija-transplant. Slovenija-transplant has very wide activities in respect of unpaid

	donation: education and information for both wide and professional public as well as concern for "PUBLIC AWARNESS" where they get the approval of Council of Europe.
SPAIN	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	It is specified in the article 3 of RD 1301/2006. It is laid down that donation of tissues and cells is voluntary and altruistic. Living donors of cells and tissues may receive compensation from the institution responsible for the collection, limited strictly to cover the costs and drawbacks arising from the procurement.
SWEDEN	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Voluntary unpaid donation are regulated in law 2006:351 and promotion of donation is regulated in law 1995:831. The National Board of Health and Welfare regulates voluntary unpaid donation in 2008:22.
TURKEY	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	
UNITED KINGDOM	
11.1 How is the principle of Voluntary Unpaid donation promoted in your country? Please describe and provide us with the legal references available	Donation of organs, tissues and cells in the UK is done on a voluntary “opt in” consent basis. Organ trafficking is illegal in the UK. Consent for donation is considered to be a positive act. The HTA has produced a Code of Practice for Consent which outlines the procedures for seeking consent and who may consent on behalf of an individual unable to give consent. The HTA, as an independent regulator, is not involved with the promotion of donation of organs, tissues or cells.

12. PERSONAL DATA PROTECTION (Article 14)

AUSTRIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	
Please describe (type of tissue, under which circumstances…)	
BELGIUM	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Article 14 of the law of December 19 2008 concerning the procurement and the use of human body material for medical use on humans or for scientifixc research. Law of December 8 1992 concerning the privacy.
BULGARIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Art.8 from Organ, tissue and cell transplantation act.
CROATIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
CYPRUS	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Donor data are confidential and can only be disclosed to the CA if requested and is under the "Protection of Personal Data Legislation"
CZECH REPUBLIC	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes

Please describe (type of tissue, under which circumstances…)	Only generaly: Tissue establishments , procurement establishments and transplantation centres must be health service establishments. The operator of these establishments is responsible for the development of the data protection and confidentiality system and for the system of disclosure (it means the disclosure because of the health service reason, if necessary).
DENMARK	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
ESTONIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
FINLAND	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	
Please describe (type of tissue, under which circumstances…)	
FRANCE	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	This legislation is clearly described in the articles L.1211-5 and R.1211-19 of the french public health code. No disclosure of the indentity in gametes and embryo donation.
GERMANY	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	
Please describe (type of tissue, under which circumstances…)	
GREECE	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
HUNGARY	

12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Act XLVII 1997 on protection of personal health data, which defines the type of sensitive data related to the therapy, the protection and data management of patients in certain cases. These are general rules and not specified for tissue or cell relation, however in Ministerial decree (18/1998) there are some special rules on medical documentation related to the donors and recipients.
IRELAND	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
ITALY	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Law 91/99 (all kind of organs and tissues). HPSCs for autologous use
LITHUANIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
MALTA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Yes, this can be found in the Tissues and Cells (Quality and Safety Regulations) (LN 271/06), in the section on: Data protection and confidentiality. 10. (1) An establishment shall ensure that all data, including genetic information, collated within the scope of the Act and any regulations made thereunder and to which third parties have access, have been rendered anonymous so that neither donors nor recipients remain identifiable.
NETHERLANDS	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	
Please describe (type of tissue, under which circumstances…)	

NORWAY	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	When a baby is born after assisted reproduction he/she at the age of 18 has the right to know the donor's identity
POLAND	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	It is allowed only for blood marrow donors and recipients.
PORTUGAL	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	
ROMANIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
SLOVAKIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
SLOVENIA	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	No
Please describe (type of tissue, under which circumstances…)	
SPAIN	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Confidentiality is laid down in article 6 of RD 1301/2006, so all personal data must be protected and guaranteed. In addition, TE must fulfil high-level measures of protection.

SWEDEN	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	Reproductive cells. Children have a right to information regarding their biological origin.
TURKEY	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	
Please describe (type of tissue, under which circumstances…)	
UNITED KINGDOM	
12.1 Does your legislation specifically state conditions for the disclosure of the identity of the recipients and/or donor? (Article 14(3))data protection	Yes
Please describe (type of tissue, under which circumstances…)	The Human Tissue (Quality and Safety for Human Application) Regulations 2007) covers all types of tissues and specifically lists 12 clauses under which information may be released. Further details for the Regulations are available at the following link: http://www.opsi.gov.uk/si/si2007/uksi_20071523_en_1

13. TESTING REQUIREMENTS (Article 19)

AUSTRIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	
NAT HIV 1	
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
BELGIUM	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes

Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	
NAT HIV 1	
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 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 is being added) testing or pathogen inactivation of the tissues or cells.
13.3 Additional comments on testing.	
BULGARIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	
NAT HIV 1	
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes

NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
CROATIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	No
13.2 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
13.3 Additional comments on testing.	
CYPRUS	

13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
CZECH REPUBLIC	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	No
Ag HIV	Yes
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes

NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	TSE examination at deceased donor of cornea, sclera or dura mater
13.3 Additional comments on testing.	
DENMARK	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	Yes
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	Yes
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	Yes
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 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 (living donor

13.3 Additional comments on testing.	
ESTONIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	
NAT HIV 1	Yes
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
FINLAND	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	

HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	Testing of risk groups as in the Directive 2006/17/EC.
FRANCE	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	Yes
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes

13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	CMV, EBV and toxoplasmosis for cells qualification ART : CMV for gamete donors
13.3 Additional comments on testing.	
GERMANY	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	Yes
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
GREECE	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes

Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
HUNGARY	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	Yes
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	Yes
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	Yes
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes

HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	for reproductive cells: Neisseria gonorrhoeae, Herpes genitalis, Cytomegalovirus, Trichomonas vaginalis
13.3 Additional comments on testing.	
IRELAND	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	
Ag HIV	
NAT HIV 1	
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	Additional tests performed depend on the outcome of the donor evaluation e.g. HTLV testing may be required depending on travel history of donor.
13.3 Additional comments on testing.	
ITALY	

13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	
NAT HIV 1	Yes
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	Yes
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	Yes
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	No
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	As agreed with tissue banks, the CNT guidelines require toxoIgM for amniotic membrane, CMV IgM for amniiotic membrane, skin and heart valves, CMV IgG for skin, HTLV 1-2 for at risks donors as foreseen by directive, CMV IgG and IgM for HPC, EBV IgG and IgM for HPC.
13.3 Additional comments on testing.	NAT tests are foreseen for living donors instead of serology at 180 days
LITHUANIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	No
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	No
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No

Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	No
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	CMV (IgM, IgG); antibodies against Toxoplasma (IgM, IgG); EBV IgG; Anti HBs
13.3 Additional comments on testing.	
MALTA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	Yes
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to	No

Directive 2006/17/EC)	
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	Liver Function Tests, Anti-CMV/Parvovirus (on request), PCR - HIV viral Load, PCR - Chlamydia, PCR - HCV, PCR - Hepatitis B.
13.3 Additional comments on testing.	Notwithstanding that NAT testing facilities are not available in Malta, PCR tesing is done including for Chlamydia.
NETHERLANDS	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
NORWAY	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	

Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	HTLV-1 for donors coming from high risk areas Test for gonorrhea for sperm donors
13.3 Additional comments on testing.	
POLAND	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	
Ag HIV	
NAT HIV 1	
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes

NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
PORTUGAL	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	Yes
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	Yes
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	Yes
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	NAT HBV and NAT HCV and NAT HIV are not compulsory for reproductive cells.
ROMANIA	

13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	Yes
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	CMV Toxoplasma Epstein Barr
13.3 Additional comments on testing.	
SLOVAKIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	
NAT HIV 1	Yes
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes

NAT HBV	
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	
SLOVENIA	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	No
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	No
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No

Please specify these other laboratory tests	
13.3 Additional comments on testing.	Request for clarification § Testing activities are conducted also in the National Blood transfusion in Slovenia and therefore they possess aparatus for NAT testing. They exposed a question during preauthorisation inspection about the need to perform test Anti HBc (which is the minimum requirement in Slovenia) if thay have a rutin practice of NAT testing for hepatitis B. We would like to get independent opinion about this question.
SPAIN	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	Yes
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	Yes
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	As for other cases mentioned above, in certain epidemiogological situations, additional tests are required, as for CMV, T.cruzi, Toxoplasma, Malaria, Dengue, VEG, HLA or RhD.
13.3 Additional comments on testing.	
SWEDEN	

13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	Yes
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	TDonors and recipients of reproductive cells: anti-HTLV I and anti-HTLV II. Sperm donors (other than regular partner): NAT or urethral culture for Neisseria gonorrhoea.e HTLVI – Cumpulsory for donors living in, or originating from, high-incidence areas or with sexual partners or parents originating from those areas.
13.3 Additional comments on testing.	Under certain circumstances additional testing may be required, e.g. malaria, tuberculosis, CMV, toxoplasmosis, EBV, T. cruzi, leishmaniasis, as well as for autosomal recessive genes connected to hereditary diseases.
TURKEY	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	Yes

Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes
HTLV-1	Yes
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	No
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests	brucella, salmonella, toxoplasma
13.3 Additional comments on testing.	
UNITED KINGDOM	
13.1 Please specify laboratory tests required for living and deceased donors in your Member State as minimum requirements	
HIV 1 and 2	
Anti-HIV 1 (Compulsory according to Directive 2006/17/EC)	Yes
Anti-HIV 2 (Compulsory according to Directive 2006/17/EC)	Yes
Anti HIV-1 and 2	No
Ag HIV	No
NAT HIV 1	No
Hepatitis B	
HBs Ag (Compulsory according to Directive 2006/17/EC)	Yes
Anti HBc (Compulsory according to Directive 2006/17/EC)	Yes
NAT HBV	No
Hepatitis C	
Anti HCV-Ab (Compulsory according to Directive 2006/17/EC)	Yes
NAT HCV	No
Treponema Pallidum (Compulsory according to Directive 2006/17/EC)	Yes

HTLV-1	No
NAT Chlamydia (form sperm donors, Compulsory according to Directive 2006/17/EC)	No
13.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
Please specify these other laboratory tests	
13.3 Additional comments on testing.	

14. SANCTIONS

AUSTRIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
BELGIUM	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
BULGARIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	Yes
If yes, what were the reasons for imposing the penalties?	Infringement of the national provisions pursuant to the Directives 2004/23, 2006/17 and 2006/86 EC.
CROATIA	

14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
CYPRUS	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
CZECH REPUBLIC	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
DENMARK	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	Yes
If yes, what were the reasons for the revocation(s) or suspension(s)?	On three occasions site licenses were re-issued with a limited expiry date (i.e. six months).
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes

If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
ESTONIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
FINLAND	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
FRANCE	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	Yes
If yes, what were the reasons for the revocation(s) or suspension(s)?	revocation of process and suspension of products (recall and suspension of products imported) : non respect of the requirement as prescribed by the EU directive and the french regulation (e.g : lack of traceability, lack of audit by the French importer, suscpicion of illegal and fraudulent activities on the procurement part, etc) - (revocation of a process) : lack of safety guarantee on the final products (sterilization process) during the assessment of the process.
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	Yes
If yes, what were the reasons for imposing the penalties?	Suspicion of illegal and fraudulent activities.
GERMANY	

14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
GREECE	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
HUNGARY	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
IRELAND	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes

If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
ITALY	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
LITHUANIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
MALTA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
NETHERLANDS	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	Yes

If yes, what were the reasons for the revocation(s) or suspension(s)?	Non compliance with legislation
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
NORWAY	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
POLAND	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	Yes
If yes, what were the reasons for the revocation(s) or suspension(s)?	In one case of one cord blood bank, the permission for the activities has been revoked due to the lack of will to fulfil the requirements regarding licensing conditions.
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	Yes
If yes, what were the reasons for imposing the penalties?	Administrative Ministry of Health decision regarding prohibition of activities of one cord blood bank due to the lack of fulfilment of national requirements for activities in the filed tissue and cell banking.
PORTUGAL	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes

If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
ROMANIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	Yes
If yes, what were the reasons for the revocation(s) or suspension(s)?	Not complying with all the requirements for the accreditation of tissue establishments – Directive 2006/86/EC – Annex 1.
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
SLOVAKIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
SLOVENIA	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
SPAIN	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or	

suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
SWEDEN	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	No
If yes, what were the reasons for imposing the penalties?	
TURKEY	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	No
If yes, have penalties already been imposed?	
If yes, what were the reasons for imposing the penalties?	
UNITED KINGDOM	
14.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Article 6(4))	No
If yes, what were the reasons for the revocation(s) or suspension(s)?	
14.2 Have penalties for infringements of the national provisions pursuant to the Directive been defined? (Article 27)	Yes
If yes, have penalties already been imposed?	Yes

If yes, what were the reasons for imposing the penalties?	During routine Phase 1 or Phase 2 inspections establishments were not carrying out procedures and practices that are in the line with the standards required under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Directions given under the Human Tissue Act 2004. Using the escalating scale described in question 7.1 appropriate regulatory sanctions were placed on the establishment's licence. In the 2007/2008 business year 127 licensing conditions were placed on 51 establisments' licences and a further 472 pieces of advice and guidance were offered to help establishments drive up their standards. In the same period, we carried out 5 Regulatory Action Panels to consider regulatory action at a higher level. Similar information for the 2008/2009 business year is currently being reviewed and analysed. Once the final results are available these will be made publically available in a Summary Inspection Report and we can provide this to the EC, on request.

15. MEDICALLY ASSISTED REPRODUCTIVE TECHNOLOGIES (MART)

AUSTRIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	Clean rooms Testing & time frames
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	At the beginning there was a massive antagonism of the concerning TE, now we have reached a point, where the implementation of the testing requirements is accepted.
BELGIUM	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
BULGARIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No

If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	Yes
Please describe	In specially created registers and donor files according to Ordinance N:28/28.6.2007.
15.3 Do you collect data concerning recipients from same donor	Yes
Please describe	In specially created registers and donor files according to Ordinance N:28/28.6.2007.
15.4 Do you collect data concerning recipients of MART treatment?	Yes
Please describe	In specially created registers and donor files according to Ordinance N:28/28.6.2007.
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	The requirements must be changed to more stringent for better public health protection.
CROATIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
CYPRUS	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	

15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
CZECH REPUBLIC	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	15.1 Too early for the answer (we started with authorisations according to directives requirements) Our national legislation was prepared with the aim to respect provisions of directives (i.e. minimal requirements) and to ensure transposition of directives in national legislation. But information appears from professionals (not yet verified at CAs) that the "transposition" of some provisions is different in different MSs; that also less stringent "transposition" of some provisions appears in national legislation od MSs. More exact information on this topic, expert arguments and analyses of these variations would be needed; if necessary, also the modification or better determination of respective provisions of directives is needed (unification of minimal requirements). Too early to be described (we started with authorisations according to directives requirements). E.g. discussion/objections appears on/against the increase of laboratory examinations, samples for laboratory examinations at the time of donation, laboratory examinations at repeat donations, separate storage.
DENMARK	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No

Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	There are 10 licensed testing centres in Danmark. Couples are expected to have been tested for infectious markers before the fertility treatment. So test centres use a requisition form for the GP to identify the tests to be performed. The testing centre needs to send a copy of results to the fertility clinic. The fertility clinics are to inform the GPs as to which testing centres are licensed, to advise the GP's to use the requisition form correctly, and to see that the GP's are providing copies of test results to the fertility clinic.
ESTONIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
FINLAND	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	According to the Directive 2006/17/EC the blood samples should be obtained at the time of donation. In parctice, the egg donors are tested before donations. The egg cells will be used directly after donation. In addition, in the case of partner donations (not direct use) fertility treatments need to be repeated several times during a short time-table. Clinics do not want to repeat viral tests at the time of every donations between partners.

	What is the acceptable time between tests (6 months, 1 year..)?
FRANCE	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	Air quality, Biological testing…
15.2 Do you collect data concerning donor's databases?	Yes
Please describe	ART : No national register for gamete donors
15.3 Do you collect data concerning recipients from same donor	Yes
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	Yes
Please describe	
15.4 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
GERMANY	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	Responsibility of the competent authorities of the german federal Laender.
15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
GREECE	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	
If yes, what are the difficulties?	

15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.4 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
HUNGARY	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
IRELAND	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	Implementation of Air Quality Requirements in ART Centres. Interpretation of 'time of donation' testing for donors of reproductive cells.
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	

15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	There have been difficulties encountered with the interpretation and implementation of 'time of donation' testing for donors of reproductives cells.
ITALY	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
LITHUANIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	As there is no consensus in the Parliament of Lithuania on the use of reproductive cells we have to admit that the transposition does not cover reproductive cells.
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.4 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	not implemented
MALTA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	Establishing the necessary core expertise to conduct inspections.
15.2 Do you collect data concerning donor's databases?	No

Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	Difficult to comment about because of the initial phase of implementation that has been reached so far.
NETHERLANDS	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	Yes
If yes, what are the difficulties?	Proof of partner
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
NORWAY	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	The testing requirements matched the tests already in place
POLAND	

15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	Poland has no experience.
PORTUGAL	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	Yes
Please describe	Databases are not yet implemented. It will include medical records and clinical characteristics. Donor' identity is anonymous and can only be disclosed by the President of CNPMA.
15.3 Do you collect data concerning recipients from same donor	Yes
Please describe	Databases are not yet implemented.
15.4 Do you collect data concerning recipients of MART treatment?	Yes
Please describe	Databases are not yet implemented. Recipients will be identified only by a code.
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	We have not yet organized experience but most of those tests were already widely used in Portuguese ART centres.
ROMANIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No

Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
SLOVAKIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
SLOVENIA	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	Yes
Please describe	For partner donation every tissue establishment has their own database. For donations other than by partners donor's base is conduct in tissue establishment, who has mandate explicitly for this activity issued by Ministry of Health according to Infertility treatment and procedures of biomedically-assisted procreation act (OG RS, No 70/2000).
15.3 Do you collect data concerning recipients from same donor	Yes
Please describe	Tissue establishment, which is authorised for allocation activities has database for donors and recipients. Additionally, according to the Infertility treatment and procedures of biomedically-assisted procreation act (OG RS, No 70/2000) it is obligatory that donor may donate reproductive cells always to the same TE and that donor can donate for live born children in maximum 2 families.

15.4 Do you collect data concerning recipients of MART treatment?	Yes
Please describe	Each tissue establishment has their own register of recipient of MART treatment.
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	There a few questions about testing on field of reproductive medicine: § Is there necessary to test donors of reproductive cells every time when a new cycle of stimulation begins. The common practice is to test the partners once a year. § Is there necessary to test both partners for all biological tests in IVF procedures. Are both partners treated as donors in IVF procedures? And how are they treated in IUI procedures, when donor is only man?
SPAIN	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.6 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
SWEDEN	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	No
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	No
Please describe	
15.3 Do you collect data concerning recipients from same donor	No
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	No
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	No indications of difficulties

TURKEY	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	
UNITED KINGDOM	
15.1 Has your Member State encountered any difficulties directly linked to MART specificities in transposing/implementing the Directives?	
If yes, what are the difficulties?	
15.2 Do you collect data concerning donor's databases?	
Please describe	
15.3 Do you collect data concerning recipients from same donor	
Please describe	
15.4 Do you collect data concerning recipients of MART treatment?	
Please describe	
15.5 What is your experience in implementing testing requirements (Annex III of Directive 2006/17) in your country?	

16. ADDITIONNAL COMMENTS – implementation

AUSTRIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	To have one line in the EU concerning MART
BELGIUM	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	The coding of tissues and cells: specific rules and date of implementation
BULGARIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
CROATIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	Lack of administrative(institutional) and technical capacity for implementation of directives.
16.2 What specific issues need to be addressed by the Commission?	Because the lack of institutional and financial resources necessary for the implementation of Directives, Craotia has applied for technical assistance – TAIEX and IPA 09. We hope that IPA project related to blood tissue and cells will be approved .
CYPRUS	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	

CZECH REPUBLIC	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	see item 3.4., 15.1., 15.4.
16.2 What specific issues need to be addressed by the Commission?	see 3.4. letter a)
DENMARK	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	The need for consistent approach to the management of commercial distributors of bone substitutes etc
16.2 What specific issues need to be addressed by the Commission?	1. The development of a Regulators forum to achieve a consensus on the technical and regulatory interpretations in this sector. 2. Organisation of a Technical Working Group for the implementation of a communication system of Quick Alerts for Competent Authorities in the TE Sector. 3. Establishment of a Working Group for the specification of a common format (i.e. model report) for the reporting of annual data from tissue establishments to their national Competent Authority. 4. Clarification on the management and controls expected for commercial distributors of human bone substitutes and skin. 5. An updated statement by the Commission on the measures adopted for the amendment of the Blood Directive to clarify lymphocytes fall within the scope of TE Directives.
ESTONIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
FINLAND	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
FRANCE	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes

If yes, what are the difficulties?	The frequency of inspection as required by article 7 of Directive 2004/23/EC :Indeed, France has numbered approximately 600 establishments that store tissues for end use (establishments that are storing tissue and/or cells for the only purpose of end use). Therefore, to cover every two years all these establishments, the necessary number of inspectors in this field is about 20. Since 2007, 60 establishments storing and distributing tissue for end use have been inspected. The results of these inspections did not highlight critical deficiencies justifying warning letters or penalty. Most of the deficiencies were related with the weakness of the quality system in place. The risk analysis has shown that the products for end use have been subject to an authorized process and tissue banks which supplied such type of products (essentially dried bones) have been inspected and authorized as well
16.2 What specific issues need to be addressed by the Commission?	Consequently an approach of inspections that are not based on a frequency purpose (every 2 years) but on a risk analysis seems more suitable for Afssaps. France wishes to see the development of a platform or network under the management and the coordination of the European Commission for : - The exchanges of information between the inspectors of the European competent authorities, - sharing feed back of experiences in terms of risk analysis and risk based inspection in this field, - scheduling joint visit inspection within EU and outside (third countries)
GERMANY	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	Discussion about the legal framework
16.2 What specific issues need to be addressed by the Commission?	
GREECE	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	The competent authority is not yet fully qualified (understaffed, no specific training, etc) and there is a need for compliance of the whole National Health System which is up to the Ministry to perform.
16.2 What specific issues need to be addressed by the Commission?	Control of import/export and commercialization of donated tissues.
HUNGARY	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If 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
16.2 What specific issues need to be addressed by the Commission?	
IRELAND	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	The interpretation of the air quality requirements to be implemented for the processing of tissues and cells has posed difficulties as the current text of the Directive with respect to air quality requirements is open to interpretation. However, the IMB has insisted on the full requirements of Annex 1 of the EU GMP guide. The interpretation of 'time of donation' testing has also provided difficulties particularly in the ART sector.
16.2 What specific issues need to be addressed by the Commission?	Clarification and guidance on the specific air quality requirements to be enforced by each member state is required i.e. full compliance with Annex 1 of the EU GMP guide.
ITALY	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
LITHUANIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	The shortage of tissue and cell specialists and lack of competent lawyers in this field had been recognized as the main difficulty of transposition. No consensus in the Parliament of Lithuania on the use of reproductive cells had been recognized as main reason for the delay.
16.2 What specific issues need to be addressed by the Commission?	
MALTA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	Still in the initial implementation phases limited by core capacity building constraints subsequent to the necessary expertise in this specialised sector.
16.2 What specific issues need to be addressed by the Commission?	Consideration of the limited administrative and human capacity resources faced by small Member States to implement the Directive especially in the light of miniscule economies

	of scale involved.
NETHERLANDS	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	Establishments are unfamiliar with the legislation What are SAE/SAR?
16.2 What specific issues need to be addressed by the Commission?	
NORWAY	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
POLAND	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	No applicable
PORTUGAL	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	The Law was published only on March 26, 2009. We needed to reorganize the National Transplant Organization, to create the news Competent Authorities and regulations and laws. It took a long time, before the news CA were able to start with the implementation.
16.2 What specific issues need to be addressed by the Commission?	
ROMANIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
SLOVAKIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	

16.2 What specific issues need to be addressed by the Commission?	
SLOVENIA	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	In Slovenia certain difficulties arise because there are three valid acts, which are connected to field of tissue and cells, Act on quality and safety of human tissues and cells, for the Purposes for medical treatment based on Directive 2004/23 (from year 2007), Infertility treatment and procedures of biomedically-assisted procreation Act (from year 2000) and The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act (from year 2000).
16.2 What specific issues need to be addressed by the Commission?	§ There is no European guideline according Article 9 (4) of the Directive 2004/23. § There is no official single European coding system according Article 25 (2) of the Directive 2004/23 developed yet. There is no exact guideline about promotion collecting cord blood considering that procurement of tissue and cells should not be a profitable. § Specificity of collecting cord blood is not enough considered in directives. § There is no obligations that contract agreement are obligatory for more wide range of activities as mentioned in article about third parties agreements (users, donor centres, agreements between different TEs. § There is no obligations for establishing users register, there is no guideline for requirements for users.
SPAIN	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	No
If yes, what are the difficulties?	
16.2 What specific issues need to be addressed by the Commission?	
SWEDEN	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	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
16.2 What specific issues need to be addressed by the Commission?	
TURKEY	

16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	financial problems
16.2 What specific issues need to be addressed by the Commission?	
UNITED KINGDOM	
16.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
If yes, what are the difficulties?	Difficulties have been encountered with understanding the detailed requirements in order for the HTA to license procurement organisations as well as those establishments solely distributing acellular material. There has been resistant from TE to implementing the full testing requirements for autologous donors of tissues and cells, especially if those donors do not have the capacity to consent. This has created a large workload for the HTA, in communicating these requirements to TE and RP and ensuring full compliance with the relevant legislation. Difficulties have been encountered with understanding the requirements for import, with regards to repeat testing and imports from 3rd Countries. We also do not have guidance on how TE export to countries with more stringent testing requirements.
16.2 What specific issues need to be addressed by the Commission?	The HTA has worked hard to develop systems that comply with the Directives only to have the EC produce guidance which requires a change to our systems. This will put an increased burden on our resources and on our TEs and RPs. The questionnaire is lengthy and requires complex data; it should be distributed earlier to ensure sufficient time is available for completion. The data required to answer the questions could have been collected from our annual activity submissions if we were made aware of this at an earlier date. The language used in the wording of questions (Q 4.1, 4.2, 4.3, 5.1 8.4, 8.6, 9.1, 14.2) is confusing and the information the question is trying to gather is ambiguous. We suggest that the wording of the questions is made more specific and the data required for submission is clearly stated. The on-line submission system in many cases does not indicate the length of answer required and is different to the word document provided.