

LIST OF NATIONAL COMPETENT AUTHORITIES FOR TISSUES AND CELLS

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Austria (AT)



Competent authority for Tissues, HPC and MAR:

Bundesamt für Sicherheit im Gesundheitswesen (BASG):
(*Austrian Federal Office for Safety in Health Care*)
Traisengasse 5 - 1200 Wien
Tel: +43-50555 -36203, -36426, -36450
Web site: <https://www.basg.gv.at>
E mail contact: gewebewigilanz@basg.gv.at



Competent Authority for manufacturing authorizations, inspections and vigilance (blood, tissues, cells, MAR, medical devices, pharmaceuticals):

Institut Überwachung (AGES)
(*Federal Office for Safety in Healthcare - Austrian Agency for Health and Food Safety*)
Traisengasse 5- 1200 Wien
Phone: +4305055536435
Website: www.ages.at
E-mail contact: inspektionen@ages.at

Belgium (BE)



Competent authority for Tissues, HPC and MAR:

Federaal Agentschap voor Geneesmiddelen en
Gezondheidsproducten (FAGG-AFMPS)
(*Federal Agency for Medicinal products and Health products*)
Avenue Galilée 5/03
1210 BRUSSELS Phone: + 32(0)25284000
Web site: <https://www.famhp.be/en>
E-mail contact: mch-mlm@fagg-afmps.be

Bulgaria (BG)



Competent authority for Tissues, HPC and MAR:

Изпълнителна агенция Медицински надзорБългарски (IAMN)

(Executive Agency Medical Supervision)

3, Sv.Georgi Sofiyski Str.- 1202 Sofia

Phone: + 35 9879011611

Web site: www.iamn.bg

E-mail contact: transplant@iamn.bg

Cyprus (CY)



Competent authority for Tissues, HPC and MAR:

Υπουργείο Υγείας της Κυπριακής Δημοκρατίας (MOH)

(Ministry of Health of Republic of Cyprus)

1 Prodromou & Chilonos Street 17

1448 Nicosia, CyprusPhone: +357 22 605 300- +357-22 605 612

Web site: www.moh.gov.cy

E-mail contact: emissouri@mphs.moh.gov.cy

Croatia (HR)



Competent authority for Tissues, HPC and MAR:

Ministarstvo zdravstva

(Ministry of Health)

Ksaver 200a - 10000 Zagreb

Phone: + 38514607555

Web site: <https://zdravstvo.gov.hr/>

Email contact: pisarnica@miz.hr

Czechia (CZ)



Competent authority for Tissues:

Koordináční Středisko Transplantací (KST)

(Czech National Transplant Coordinating Centre)

Ruska 85 - 11000 Praha 10

Phone: + 420271019345

Web site: www.kst.cz

E-mail contact: info@kst.cz



Competent authority for Tissues, HPC and MAR:

Ministerstvo zdravotnictví České republiky (MZCR)

(Ministry of Health of the Czech Republic)

Palackého nám. 4 - 12801 Praha 2

Phone: + 420224971111

Web site: www.mzcr.cz

E-mail contact: mzcr@mzcr.cz



Competent authority for surveillance over biological material processing (Tissue, HPC and ART):

Státní ústav pro kontrolu léčiv (SULK)

(State Institute for Drug Control)

Šrobárova 48 - 10041 Praha 10
Phone: + 420272185642
Web site: www.sukl.cz
E-mail contact: posta@sukl.cz

Denmark (DK)



Competent Authority for Tissues, HPC and MAR:

Styrelsen for Patientsikkerhed (STPS)
(Danish Patient Safety Authority)
Islands Brygge 67 – DK-2300 København S
Phone: + 45 72 28 66 00
Fax: +4572227414
Website: <https://stps.dk/>
E-mail: stps@stps.dk

Estonia (EE)



Competent authority for Tissues, HPC and MAR:

Ravimiamet (Republic of Estonia Agency of Medicines)
Nooruse 1 - 50411 Tartu
Phone: + 3727374140
Web site: www.ravimiamet.ee
E-mail contact: info@ravimiamet.ee

Competent Authority for the transplantation process:

Sotsiaal Ministerium – Tervishoiuosakond
(Ministry of Social Affairs, Department of Health Care)
Gonsiori 29 – 15027 Tallin
Phone: + 3726269301
Web site: www.sm.ee
E-mail contact: info@sm.ee



3

Finland (FI)



Competent authority for Tissues, HPC and MAR:

Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)
(Finnish Medicines Agency)
Mannerheimintie 103b - P.O. Box 55 - FI-00304 Helsinki
Phone: +358295223341
Web site: www.fimea.fi
E-mail contact: registry@fimea.fi

France (FR)



Competent authority for Tissues, HPC and MAR:

Agence de la Biomédecine (ABM)

(*French Biomedicine Agency*)

1 Avenue du Stade de France - 93212 Saint-Denis la Plaine Cédex

Phone: + 33(0)155936901/6523

Web site: www.agence-biomedecine.fr

E-mail contact: communication@biomedecine.fr



Competent authority for authorization and inspection for Tissues and HPC, authorization and inspection of clinical trials, management of the biovigilance system:

Agence Nationale de Sécurité du Médicament (ANSM)

(*National Agency for Medicines and Health Products Safety*)

143-147 Boulevard Anatole France - 93285 Saint Denis Cedex

Phone: + 33(0)155873000

Fax: + 33(0)155873012

Web site: www.ansm.sante.fr

E-mail contact: aec.pbet@ansm.sante.fr



Competent authority for the authorization of procurement and transplantation establishments (Tissues and HPC):

Agence Régionale de Santé (ARS) (*Regional Health Agency*)

14, avenue Duquesne

75350 PARIS 07 SP

Phone: 0033(0)140566000

Web site: <http://ars.sante.fr>



Competent authority for Tissues, HPC and MAR:

Ministère Des Solidarités Et De La Santé

(*Ministry of Solidarity and Health*)

14, avenue Duquesne

75350 PARIS 07 SP

Phone: 0033(0)140566000

Web site: <https://solidarites-sante.gouv.fr/>

Germany (DE)



Competent authority for Tissues, HPC and MAR:

Bundesministerium für Gesundheit (BMG)

(*Federal Ministry of Health*)

Heilsbachstraße 18 - 53123 Bonn

Phone: + 49228994411151

Web site: www.bmg.bund.de

E-mail contact: 312@bmg.bund.de



Competent authority for Tissues, HPC and MAR:

Paul-Ehrlich-Institut (PEI)

(*Division of Medical Biotechnology*)

Paul-Ehrlich-Str. 51-53 - D-63225 Langen

Phone: + 496103770

Web site: www.pei.de

E-mail contact: pei@pei.de

Greece (GR)



Competent authority for Tissues and HPC:

Εθνικός Οργανισμός Μεταμοσχεύσεων (EOM)
(*Hellenic Transplant Organization*)

An. Tsocha 5 - 11521 Athens

Phone: +30 2132027000-001

Web site: www.eom.gr

E-mail contact: eom@eom.gr



Competent authority for MAR:

Εθνική Αρχή Ιατρικώς Υποβοηθούμενης Αναπαραγωγής (EAIYA)
(*Greek National Authority of Assisted Reproduction*)

3 Ploutarchou St, 10675 Athens Phone: +30 213 207 2003

Web site: <http://eaiya.gov.gr>

E-mail contact: secretary@eaiya.gov.gr

Hungary (HU)



Competent authority on Tissues and Cells:

Nemzeti Népegészségügyi és Gyógyszerészeti Központ
(*National Center for Public Health and Pharmaceuticals*)

1097 Budapest, Albert Flórián út 2-6.

Phone: +3614761100

Web site: <https://nngyk.gov.hu/>

E-mail contact: info@egeszsegvonat.gov.hu

Ireland (IE)



Competent authority for Tissues, HPC and MAR:

The Health Products Regulatory Authority (HPRA)

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace - Dublin 2

Phone: + 35316764971

Fax: + 35316767836

Web site: www.hpra.ie

E-mail contact: info@hpra.ie

Iceland (IS)



Competent authority for Tissues, HPC and MAR:

Lyfjastofnun (*The Icelandic Medicines Agency*)

Vínlandsleið 14

113 Reykjavík

Phone: +354 520 2100

Fax: +354 561 2170

Website: www.ima.is

Email: laekningataeki@lyfjastofnun.is

Italy (IT)



Centro Nazionale Trapianti

Competent authority for Tissues, HPC transplantation and MAR:

Centro Nazionale Trapianti (CNT)
(*Italian National Transplant Center*)
Viale Regina Elena 299 - 00161 Roma
Phone: + 39(0)649904040-4041
Fax: + 39(0)649904101
Web site: www.trapianti.salute.gov.it
E-mail contact: cnt@iss.it



Competent authority for HPC:

Centro Nazionale Sangue (CNS)
(*Italian National Blood Center*)
Viale Regina Elena 299 - 00161 Roma
Phone: + 39(0)649904989
Fax: + 39(0)649904975
Web site: www.centronazionale sangue.it
E-mail contact: direzione.cns@iss.it

Latvia (LV)



Zāļu novērtēšana, reģistrēšana, uzraudzība,
kontrolē un izplatīšanas regulēšana valstī

Competent authority for Tissues, HPC and MAR under the supervision of the Ministry of Health of the Republic of Latvia:

Zāļu Valsts Aģentūra (ZVA)
(*State Agency of Medicines of the Republic of Latvia*)
Jersikas street 15, Riga, LV-1003, Latvia
Phone: +37167078424
Web site: www.zva.gov.lv
E-mail contact: info@zva.gov.lv

6

Lithuania (LT)



Competent authority for Tissues and HPC:

Nacionalinis Transplantacijos Biuras (NBT)
(*National Transplantation Bureau*)
Santariskiu str. 2 - LT-08661 Vilnius
Phone: + 37052796096
Fax: +37052796096
Web site: ntb.lrv.lt
E-mail contact: info@transplantacija.lt

Luxembourg (LU)



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Competent authority for Tissues, HPC and MAR:

Ministère de la Santé - Direction de la Santé (MS-EATAT)
(*Ministry of Health*)
Allée Marconi - Villa Louvigny - L-2120 Luxembourg
Phone: (+352) 247-85500
Fax: (+352) 467692
Web site: <https://sante.public.lu/fr.html>
E-mail contact: mss@mss.etat.lu

Macedonia (MK)



Competent authority:

Министерството за здравство на Република Македонија
(*Ministry of Health of the Republic of Macedonia*)
Vodnjanska bb - 1000 Skopje
Phone: +389(02)3112500
Fax: +389(02)3296522
Web site: www.moh.gov.mk

Republic of Moldova (MD)



Competent authority for Tissues and HPC:

Agenția de Transplant (MD)
(*The Transplant Agency*)
N.Testemitanu, 29 - MD-2000 Chisinau
Phone: + 37322286466
Fax: +37322286466
Web site: www.transplant.gov.md
E-mail contact: atm@ms.md

Malta (MT)



Competent authority for Tissues, HPC and MAR:

Health Care Services Standards Directorate (DHCSS)
(*Ministry for health, elderly and community care*)
Public Health Regulation Department - St Luqa Hospital - OPD
(Level 1)
St. Luke's Square - G'Mangia, PTA1010 Malta
Phone: + 35625953328
Fax: +35625953327
Web site: www.healthstandards.gov.mt
E-mail contact: dhcss.mhec@gov.mt

7

Netherlands (NL)



Ministry of Health, Welfare and Sport

Competent authority for Tissues, HPC and MAR:

Ministerie van Volksgezondheid, Welzijn en Sport (MINVWS)
(Minister of Health, Welfare and Sport)
Parnassusplein 5 - 2511 VX The Hague
Phone: + 31(0)703407911
Fax: + 31(0)703407834
Web site: www.minvws.nl

Competent Authority for the Inspections:

Inspectie voor de Gezondheidszorg (IGZ)
(The Health Care Inspectorate)
Magistratenlaan 222 - 5223 MA 's-Hertogenbosch
Phone: +31 73 620 0300
Fax: +31 088-120 50 01
Website: <http://www.igz.nl>
E-mail contact: meldpunt@igz.nl

Norway (NO)



Competent authority for Tissues, HPC and MAR:

Helsedirektoratet (HDIR) (*The Directorate for Health*)
Directorate of Health, PO Box 220, Skøyen, 0213 Oslo
Phone: (+47) 47 47 20 20
Web site: www.helsedirektoratet.no
E-mail contact: postmottak@helsedir.no



Competent authority for Tissues or/and Cells used in Medical Products:

Direktoratet for medisinske produkter (NoMA)
(Norwegian Medical Products Agency)
Grensesvingen 26 0663 Oslo
Phone: (+47) 22 89 77 00
Web site: www.noma.no
E-mail contact: post@noma.no

Poland (PL)



Competent Authority for HPC (from bone marrow) and registry for cord blood

Polish Transplant Coordinating Center Poltransplant
Al. Jerozolimskie 87 - 02-001 Warsaw
Phone: + 48226225806
Fax: + 48226223243
Web site: www.poltransplant.org.pl
E-mail contact: transpl@poltransplant.org.pl



Competent Authority for Tissues and Cells other than HPC

Krajowe Centrum Bankowania Tkanek i Komrek (NCTCB)
(*National Centre of Tissue and Cell Banking*)
Chalubinskiego 5 - 02-004 Warsaw
Phone: + 48(22)6217543
Fax: + 48(22)6217543
Web site: www.kcbtik.pl
E-mail contact: sekretariat@kcbtik.pl

Portugal (PT)



Competent Authority for Tissues and HPC (Only for import/export):

Instituto Português do Sangue e da Transplantação (IPST)
(*Institute for Blood and Transplantation Services*)
Avenida Miguel Bombarda 6 - 1000-208 Lisboa
Phone: +351210063057
Fax: +351210063370
E-mail contact: transplantacao@ipst.min-saude.pt
Website: www.ipst.pt

**Competent authority for MAR:**

Conselho Nacional de Procriação Medicamente Assistida
(CNPMA) (*National Council for Medically Assisted Procreation*)
Palácio de São Bento - 1249-068 Lisboa
Phone: + 351213919303
Fax: + 351213917502
Web site: www.cnpma.org.pt
E-mail contact: CNPMA.Correio@ar.parlamento.pt

**Competent authority for Tissues, HPC and MAR:**

Direção-Geral da Saúde (DGS)
(*Directorate-General of Health*)
Alameda D. Afonso Henriques 45 - 1049-005 Lisboa
Phone: +351218430500
Fax: +351218430530
Web-site: www.dgs.pt
E-mail contact: sanguetransplantacao@dgs.pt

Romania (RO)**Competent authority for Tissues, HPC and MAR:**

Agentia Națională de Transplant (ANT) (*National Transplant Agency*)
Str. Constantin Caracas 2-8, Sector 1 - 011155 Bucurest
Phone: + 40317101473
Fax: + 40317101475
Web site: www.transplant.ro
E-mail contact: ant@transplant.ro

**Competent Authority for Tissues and HPC Inspections:**

Direcția de Control în Sănătate Publică (DCSPMS)
(*Department of Control in Public Health - National Transplant Agency*)
Cristian Popișteanu 1-3, Sector 1 - 010024 Bucurest
Phone: + 40213072557
Fax: + 40213072048
Web site: www.ms.ro
E-mail contact: dcspms@ms.ro

Slovakia (SK)**Competent authority for Tissues, HPC and MAR:**

Ministerstvo Zdravotníctva Slovenskej Republiky
(*Ministry of Health*)
Limbová 2, P.O. BOX 52 - 83752 Bratislava 37
Phone: +421 2 593 73 111
Fax: +421 2 547 77 983
Web site: www.health.gov.sk
E-mail contact: office@health.gov.sk

Slovenia (SI)



Competent Authority for Tissues, HPC and MAR Authorization and Inspection:

Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP) (*Agency for Medicinal Products and Medical Devices of the Republic of Slovenia*)
Slovenčeva ulica 22 - SI-1000 Ljubljana
Phone: + 386(0)82000500
Fax: + 38682000510
Web site: www.jazmp.si
E-mail contact: info@jazmp.si

Spain (ES)



Competent authority for Tissues and HPC:

Organización Nacional de Trasplantes (ONT)
(*National Transplant Organization*)
Calle Sinesio Delgado 6-8, pabellón 3, planta 1º - 28029 Madrid
Phone: + 34918224913
Web site: www.ont.es
E-mail contact: ont@sanidad.gob.es



Competent authority for MAR:

Ministerio de Sanidad
(Ministry of Health)
Paseo del Prado 18-20 – 28071. Madrid
Phone: +34 91 596 10 00
E-mail contact: sgcfc@sanidad.gob.es
Web site: <https://www.sanidad.gob.es/>

Sweden (SE)



Competent authority for Tissues, HPC and MAR:

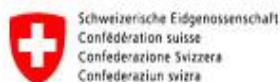
Health and Social Care Inspectorate (IVO)
P.O. Box 6202 - 10243 Stockholm
Phone: +46107885000
Web site: www.ivo.se
E-mail contact: registrator@ivo.se



Competent Authority for Tissues and/or HPC used in Medical Products:

Läkemedelsverket (MPA) (*Medical Products Agency*)
P.O. Box 26 - SE-75103 Uppsala
Phone: + 4618174600
Fax: + 4618548566
Web site: www.lakemedelsverket.se
E-mail contact: registrator@mpa.se

Switzerland (CH)



Competent authority for Tissues, HPC and MAR:

Bundesamt für Gesundheit - Sektion Transplantation und Fortpflanzungsmedizin/ Office fédéral de la santé publique - Section Transplantation et Procréation Médicalement assistée (FOPH/BAG) (*Federal Office for Public Health – Sub-Division Transplantation and Reproductive Medicine*)
Schwarzenburgstrasse 157 - CH-3003 Bern
Phone: +41584635154
Fax: +41584626233
Web site: www.bag.admin.ch
E-mail contact: info@bag.admin.ch

Competent authority for MAR:

Federal Department of Home Affairs (FDHA)
Federal Statistical Office
Section Population Health
Espace de l'Europe 10, CH-2010 Neuchâtel
Phone: +41 58 460 59 50
Web site: <https://www.bfs.admin.ch/bfs/en/home.html>

Turkey (TR)



Competent authority for Tissues and HPC:

T.C. Sağlık Bakanlığı
(*Tissue and Cell Transplantation Unit, Curative Services - Ministry of Health*)
Sağlık Bakanlığı /Tedavi Hizmetleri Genel Müdürlüğü/Doku ve Hücre Nakli Hizmetleri Şubesi Mithatpaşa Cad. B Blok Kat:3
Numara 8 – Sıhhiye, Ankara
Phone: + 903125851509
Fax: + 903125851566
Web site: www.saglik.gov.tr
E-mail contact: info@saglik.gov.tr



Competent Authority for ART:

Sağlık Bakanlığı (*Ministry of Health*)
Mithatpaşa Cad. No: 3 - 06434 Sıhhiye, Ankara
Phone: +903125851487
Fax: +903125851566
Website: www.saglik.gov.tr
E-mail contact: info@saglik.gov.tr



Competent Authority for tissues, non-ART cells and organs:

Human Tissue Authority (HTA)

2 Redmand Place, London, E20 1JQ

Phone: + 4402072691900

Fax: + 4402072691999

Web site: www.hta.gov.uk

E-mail contact: enquiries@hta.gov.uk,

licensing.enquiries@hta.gov.uk



Competent authority for ART:

Human Fertilisation and Embryology Authority (HFEA)

10 Spring Gardens- London SW1A 2BU

Phone: + 44 (0)20 7291 8200

Fax: + 44 (0)20 7291 8201

Web site: www.hfea.gov.uk

E-mail contact: admin@hfea.gov.uk