

CONTACT E-MAIL ADDRESSES FOR SUBMISSION OF ELECTRONIC RESPONSE DOCUMENTS DURING MUTUAL RECOGNITION & DECENTRALISED PROCEDURES

(The list is provided to assist pharmaceutical companies identifying a contact e-mail address for submission of electronic response documents for applications for marketing authorisations, variations and renewals in Mutual Recognition and Decentralised Procedures in each Member State.

The names and addresses of the CMD(h) Members should not be used for the submission of response documents)

COUNTRY	ADDRESS	PROCEDURE	E-MAIL <i>Subject: Procedure Nr._Product Name_ Document title</i>
AUSTRIA	Federal Agency for Safety in Health Care AGES PharmMed LCM Schnirchgasse 9 A-1030 VIENNA	MA applications	responses@ages.at
		Variations	
		Renewals	
BELGIUM	Federal Agency for Medicines and Health Products Eurostation II Place Victor Horta, 40 Boite 40 B-1060 Brussels Belgium	MA applications	Gestion.Fagg-Afmps@fagg.be
		Variations	
		Renewals	
BULGARIA	Bulgarian Drug Agency 26 Yanko Sakazov Blvd 1504 Sofia Bulgaria	MA applications	tzvetomir.deliyski@bda.bg
		Variations	diana.katrandzhieva@bda.bg
		Renewals	tzvetomir.deliyski@bda.bg
CYPRUS	Ministry of Health Pharmaceutical Services 7 Larnacos Avenue CY – 1475 Nicosia Lefkosia	MA applications	spetridou@phs.moh.gov.cy
		Variations	ptriantafyllis@phs.moh.gov.cy
		Renewals	spetridou@phs.moh.gov.cy
CZECH REPUBLIC	State Institute for Drug Control Srobarova 48 CZ – 100 41 Praha 10	MA applications	mrp@sukl.cz
		Variations	
		Renewals	
DENMARK	Danish Medicines Agency Axel Heides Gade 1 DK-2300 Copenhagen	MA applications	God-afdelingspostkasse@dkma.dk
		Variations	
		Renewals	
ESTONIA	State Agency of Medicines 1 Nooruse Street EE-50411 Tartu Estonia	MA applications	mrp@sam.ee
		Variations	
		Renewals	
FINLAND	National Agency for Medicines P.O. Box 55 (Mannerheimintie 103b) FIN - 00301 HELSINKI	MA applications	mrp@nam.fi
		Variations	
		Renewals	

COUNTRY	ADDRESS	PROCEDURE	E-MAIL <i>Subject: Procedure Nr., Product Name, Document title</i>
FRANCE	Agence française de sécurité sanitaire des produits de santé (Afssaps) 143-147 bd Anatole France FR-93285 SAINT-DENIS CEDEX	MA applications	ueurop@afssaps.sante.fr
		Variations	
		Renewals	
GERMANY	Federal Institute for Drugs and Medical Devices BfArM Kurt-Georg Kiesinger-Allee 3 D-53175 Bonn	MA applications	mrp@bfarm.de
		Variations	mrp-var@bfarm.de
		Renewals	mrp-ren@bfarm.de
GERMANY (sera, vaccines, blood preparations)	Paul Ehrlich Institute Paul Ehrlich Str. 51-59 D - 63225 LANGEN	MA applications	eu-cooperation@pei.de
		Variations	
		Renewals	
GREECE	National Organization for Medicines Registration Division Mesogion Avenue 284 Holargos GR - ATHENS 15562	MA applications	The contact point for the procedure
		Variations	
		Renewals	
HUNGARY	National Institute of Pharmacy Zrinyi U. 3 H-1051 Budapest	MA applications	HU as CMS: mrp-dcp-new-cms@ogyi.hu HU as RMS: mrp-dcp-new-rms@ogyi.hu
		Variations	HU as CMS: mrp-dcp-var-cms@ogyi.hu HU as RMS: mrp-dcp-var-rms@ogyi.hu
		Renewals	HU as CMS: mrp-dcp-renew-cms@ogyi.hu HU as RMS: mrp-dcp-renew-rms@ogyi.hu
ICELAND	Iceland Medicines Control Agency Eidistorg 13-15 P.O.Box 180 172 Seltjarnarnes Iceland	MA applications	IS as CMS: inga@imca.is IS as RMS: thorbjorg.kjartansdottir@lyfjastofnun.is
		Variations	IS as CMS : inga@imca.is
		Renewals	
IRELAND	Irish Medicines Board The Earlsfort Centre Earlsfort Terrace IR - DUBLIN 2	MA applications	eulicensingcomments@imb.ie
		Variations	
		Renewals	
ITALY	Agenzia Italiana del Farmaco Via Sierra Nevada, 60 IT - 00144 Roma	MA applications	The contact point for the procedure or: g.pugliese@aifa.gov.it
		Variations	The contact point for the variation or: t.demarco@aifa.gov.it
		Renewals	f.mazzeo@aifa.gov.it
LATVIA	State Agency of Medicines Jersikas iela 15 LV – 1003 Riga	MA applications	MRP-DCP@zva.gov.lv
		Variations	Variations_MRP-DCP@zva.gov.lv
		Renewals	Renewals_MRP-DCP@zva.gov.lv

COUNTRY	ADDRESS	PROCEDURE	E-MAIL <i>Subject: Procedure Nr._ Product Name_ Document title</i>
LIECHTENSTEIN	Amt für Gesundheit Äulestrasse 51 P.O.Box 684 FL-9490 Vaduz Principality of Liechtenstein	MA applications	info@alkvw.llv.li
		Variations	
		Renewals	
LITHUANIA	State Medicines Control Agency 9/1 Traku Str. LT – 01132 Vilnius	MA applications	response@vvt.lt
		Variations	
		Renewals	
LUXEMBOURG	Direction de La Santé Villa Louvigny Division de la Pharmacie et des Medicaments Allée Marconi L- 2120 Luxembourg	MA applications	The contact point for the procedure
		Variations	
		Renewals	
MALTA	Medicines Authority Licensing Directorate 198 Rue D'Argens GZR 03 Gzira	MA applications	mrp-dcp.adm@gov.mt
		Variations	
		Renewals	
THE NETHERLANDS	Medicines Evaluation Board Kalvermarkt 53 P.O.Box 16229 NL-2500 BE Den Haag	MA applications	case@cbg-meb.nl <i>The casenumber [xxxx] should be added in the subjectheader of the e-mail. A casenumber is given to the applicant immediately after receipt of an application and should be used in all further correspondence.</i>
		Variations	
		Renewals	
NORWAY	The Norwegian Medicines Agency Sven Oftedalsvei 8 N-0950 Oslo	MA applications	MT@noma.no
		Variations	
		Renewals	
POLAND	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 41 Zabkowska Str. 03-736 Warsaw, Poland	MA applications	mrp.dcp@urpl.gov.pl
		Variations	variations@urpl.gov.pl
		Renewals	renewals@urpl.gov.pl
PORTUGAL	INFARMED Parque de Saúde de Lisboa Avenida do Brasil, nº 53 P - 1700 LISBOA	MA applications	dmps-cmt@infarmed.pt
		Variations	
		Renewals	dmps-med@infarmed.pt
ROMANIA	National Medicines Agency 48, Av. Sanatescu 011478 Bucharest Romania	MA applications	mrp-dcp.responses@anm.ro
		Variations	
		Renewals	
SLOVAK REPUBLIC	State Institute for Drug Control Kvetná 11 SK – 825 08 Bratislava 26	MA applications	eu.registracia@sukl.sk
		Variations	
		Renewals	
SLOVENIA	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia Mali trg 6 SI-1000 Ljubljana, Slovenia	MA applications	mrp.arszmp@gov.si
		Variations	
		Renewals	
SPAIN	Agencia Española del	MA applications	MA_Applications@agemed.es

COUNTRY	ADDRESS	PROCEDURE	E-MAIL <i>Subject: Procedure Nr. Product Name Document title</i>
	Medicamento y Productos Sanitarios Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1, 28022 Madrid España	Variations	variations@agemed.es
		Renewals	renewals@agemed.es
SWEDEN	Medical Products Agency Dag Hammarskjölds väg 42 S - 751 03 UPPSALA	MA applications	sok.central@mpa.se
		Variations	
		Renewals	
UNITED KINGDOM	Medicines and Healthcare products Regulatory Agency Market Towers 1 Nine Elms Lane UK - LONDON SW8 5NQ	MA applications	MR-DCprocedures@mhra.gsi.gov.uk
		Variations	
		Renewals	