

## CONTACT ADDRESSES FOR SUBMISSION OF TRANSLATIONS IN MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

(The list is provided to assist pharmaceutical companies identifying a contact point for submission of translations for applications for marketing authorisation, type II variations and renewals in Mutual Recognition and Decentralised Procedures in each Member State)

COUNTRY	ADDRESS	PROCEDURE	E-MAIL
			<i>Subject: Procedure Nr._Product Name_National translations</i>
AUSTRIA	Federal Agency for Safety in Health Care AGES PharmMed LCM Schnirchgasse 9 A-1030 VIENNA	MA applications	<a href="mailto:mrp-spc@ages.at">mrp-spc@ages.at</a>
		Variations	
		Renewals	
BELGIUM	Federal Agency for Medicines and Health Products Eurostation II Place Victor Horta, 40 Boite 40 B-1060 Brussels Belgium	MA applications	<a href="mailto:fagg_closing_file@fagg.be">fagg_closing_file@fagg.be</a>
		Variations	
		Renewals	
BULGARIA	Bulgarian Drug Agency 8, Damyán Gruev Str. 1303 Sofia Bulgaria	MA applications	<a href="mailto:vladislav.galabov@bda.bg">vladislav.galabov@bda.bg</a>
		Variations	<a href="mailto:margarita.kovachka@bda.bg">margarita.kovachka@bda.bg</a>
		Renewals	<a href="mailto:vladislav.galabov@bda.bg">vladislav.galabov@bda.bg</a>
CYPRUS	Ministry of Health Pharmaceutical Services 7 Larnacos Avenue CY – 1475 Nicosia Lefkosia	MA applications	<a href="mailto:spetridou@phs.moh.gov.cy">spetridou@phs.moh.gov.cy</a>
		Variations	<a href="mailto:ptriantafyllis@phs.moh.gov.cy">ptriantafyllis@phs.moh.gov.cy</a>
		Renewals	<a href="mailto:spetridou@phs.moh.gov.cy">spetridou@phs.moh.gov.cy</a>
CZECH REPUBLIC	State Institute for Drug Control Srobarova 48 CZ – 100 41 Praha 10	MA applications	<a href="mailto:mrp@sukl.cz">mrp@sukl.cz</a>
		Variations	
		Renewals	
DENMARK	Danish Medicines Agency Axel Heides Gade 1 DK-2300 Copenhagen	MA applications	<a href="mailto:god-afdelingspostkasse@dkma.dk">god-afdelingspostkasse@dkma.dk</a>
		Variations	
		Renewals	
ESTONIA	State Agency of Medicines 1 Nooruse Street EE-50411 Tartu Estonia	MA applications	<a href="mailto:mrp@sam.ee">mrp@sam.ee</a>
		Variations	
		Renewals	
FINLAND	Finnish Medicines Agency P.O. Box 55	MA applications	<a href="mailto:mrp@fimea.fi">mrp@fimea.fi</a>
		Variations	

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	(Mannerheimintie 103b) FIN - 00301 HELSINKI	Renewals	
FRANCE	<b>Agence française de sécurité sanitaire des produits de santé (Afssaps)</b> 143-147 bd Anatole France FR-93285 SAINT- DENIS CEDEX	MA applications	<a href="mailto:ueurop@afssaps.sante.fr">ueurop@afssaps.sante.fr</a>
		Variations	
		Renewals	
GERMANY	<b>Federal Institute for Drugs and Medical Devices</b> BfArM Kurt-Georg Kiesinger-Allee 3 D-53175 Bonn	MA applications	<a href="mailto:translations@bfarm.de">translations@bfarm.de</a>
		Variations	
		Renewals	
GERMANY (sera, vaccines, blood preparations)	<b>Paul Ehrlich Institute</b> Paul Ehrlich Str. 51- 59 D - 63225 LANGEN	MA applications	<a href="mailto:eu-cooperation@pei.de">eu-cooperation@pei.de</a>
		Variations	
		Renewals	
GREECE	<b>National Organization for Medicines</b> Registration Division Mesogion Avenue 284 Holargos GR - ATHENS 15562	MA applications	<a href="mailto:spctrans@eof.gr">spctrans@eof.gr</a>
		Variations	
		Renewals	
HUNGARY	<b>National Institute of Pharmacy</b> Zrínyi U. 3 H-1051 Budapest	MA applications	<a href="mailto:mrp-dcp-new-cms@ogyi.hu">mrp-dcp-new-cms@ogyi.hu</a> <a href="mailto:mrp-dcp-new-rms@ogyi.hu">mrp-dcp-new-rms@ogyi.hu</a>
		Variations	<a href="mailto:mrp-dcp-var-cms@ogyi.hu">mrp-dcp-var-cms@ogyi.hu</a> <a href="mailto:mrp-dcp-var-rms@ogyi.hu">mrp-dcp-var-rms@ogyi.hu</a>
		Renewals	<a href="mailto:mrp-dcp-renew-cms@ogyi.hu">mrp-dcp-renew-cms@ogyi.hu</a> <a href="mailto:mrp-dcp-renew-rms@ogyi.hu">mrp-dcp-renew-rms@ogyi.hu</a>
ICELAND	<b>Iceland Medicines Agency</b> Eidistorg 13-15 170 Seltjarnarnes Iceland	MA applications	<a href="mailto:textar@lyfjastofnun.is">textar@lyfjastofnun.is</a> cc : <a href="mailto:inga@ima.is">inga@ima.is</a>
		Variations	
		Renewals	
IRELAND	<b>Irish Medicines Board</b> The Earlsfort Centre Earlsfort Terrace IR - DUBLIN 2	MA applications	<a href="mailto:eulicensingcomments@imb.ie">eulicensingcomments@imb.ie</a>
		Variations	<a href="mailto:Cathy.hempenstall@imb.ie">Cathy.hempenstall@imb.ie</a>
		Renewals	<a href="mailto:Rachel.orourke@imb.ie">Rachel.orourke@imb.ie</a>
ITALY	<b>Agenzia Italiana del Farmaco</b> Via del Tritone, 181 IT - 00187 Roma	MA applications	<a href="mailto:stampati.aic_mr-dc@aifa.gov.it">stampati.aic_mr-dc@aifa.gov.it</a>
		Variations	<a href="mailto:stampati.var2-mr@aifa.gov.it">stampati.var2-mr@aifa.gov.it</a>
		Renewals	<a href="mailto:f.mazzeo@aifa.gov.it">f.mazzeo@aifa.gov.it</a>
LATVIA	<b>State Agency of Medicines</b> Jersikas iela 15 LV – 1003 Riga	MA applications	<a href="mailto:Translations_MRP-DCP@zva.gov.lv">Translations_MRP-DCP@zva.gov.lv</a>
		Variations	
		Renewals	

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LIECHTENSTEIN	Amt für Gesundheit Äulestrasse 51 P.O.Box 684 FL-9490 Vaduz Principality of Liechtenstein	MA applications	<a href="mailto:info@alkvw.llv.li">info@alkvw.llv.li</a>
		Variations	
		Renewals	
LITHUANIA	State Medicines Control Agency 9/1 Traku Str. LT – 01132 Vilnius	MA applications	<a href="mailto:registracija@vvkt.lt">registracija@vvkt.lt</a>
		Variations	
		Renewals	
LUXEMBOURG	Direction de La Santé Villa Louvigny Division de la Pharmacie et des Medicaments Allée Marconi L- 2120 Luxembourg	MA applications	<a href="mailto:Jacqueline.Genoux-Hames@ms.etat.lu">Jacqueline.Genoux-Hames@ms.etat.lu</a>
		Variations	
		Renewals	
MALTA	Medicines Authority Licensing Directorate 198 Rue D'Argens GZR 03 Gzira	MA applications	Not applicable
		Variations	
		Renewals	
THE NETHERLANDS	Medicines Evaluation Board Kalvermarkt 53 P.O.Box 16229 NL-2500 BE Den Haag	MA applications	<a href="mailto:case@cbg-meb.nl">case@cbg-meb.nl</a>  <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	<a href="mailto:MT@noma.no">MT@noma.no</a>
		Variations	
		Renewals	
POLAND	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 41 Zabkowska Str. 03-736 Warsaw, Poland	MA applications	<a href="mailto:mrp.dcp@urpl.gov.pl">mrp.dcp@urpl.gov.pl</a>  <a href="mailto:variations@urpl.gov.pl">variations@urpl.gov.pl</a>  <a href="mailto:renewals@urpl.gov.pl">renewals@urpl.gov.pl</a>
		Variations	
		Renewals	
PORTUGAL	INFARMED Parque de Saude de Lisboa Avenida do Brasil, n° 53 P - 1700 LISBOA	MA applications	<a href="mailto:dmps.cmt@infarmed.pt">dmps.cmt@infarmed.pt</a>
		Variations	
		Renewals	
ROMANIA	National Medicines Agency 48, Av. Sanatescu 011478 Bucharest Romania	MA applications	<a href="mailto:mrp-dcp.translations@anm.ro">mrp-dcp.translations@anm.ro</a>
		Variations	
		Renewals	
SLOVAK REPUBLIC	State Institute for Drug Control Kvetná 11 SK – 825 08 Bratislava 26	MA applications	<a href="mailto:eu.registracia@sukl.sk">eu.registracia@sukl.sk</a>
		Variations	
		Renewals	

COUNTRY	ADDRESS	PROCEDURE	E-MAIL <i>Subject: Procedure Nr._Product Name_National translations</i>
SLOVENIA	<b>Agency for Medicinal Products and Medical Devices of the Republic of Slovenia</b> Ptujška ulica 21 SI-1000 Ljubljana, Slovenia	MA applications	<a href="mailto:mrp_dcp@jazmp.si">mrp_dcp@jazmp.si</a>
		Variations	
		Renewals	
SPAIN	<b>Agencia Española del Medicamento y Productos Sanitarios</b> Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1 28022 Madrid España	MA applications	<a href="mailto:maapplications@aemps.es">maapplications@aemps.es</a>
		Variations	<a href="mailto:eudramrve@es-v.eudra.org">eudramrve@es-v.eudra.org</a>
		Renewals	<a href="mailto:eudramrve@es-v.eudra.org">eudramrve@es-v.eudra.org</a>
SWEDEN	<b>Medical Products Agency</b> Dag Hammarskjölds väg 42 S - 751 03 UPPSALA	MA applications	<a href="mailto:sok.central@mpa.se">sok.central@mpa.se</a>
		Variations	
		Renewals	
UNITED KINGDOM	<b>Medicines and Healthcare products Regulatory Agency</b> Market Towers 1 Nine Elms Lane UK - LONDON SW8 5NQ	MA applications	<a href="mailto:MR-DCprocedures@mhra.gsi.gov.uk">MR-DCprocedures@mhra.gsi.gov.uk</a>
		Variations	
		Renewals	