

GMP Sector under the MRAs/ Conformity Assessment Bodies

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Update of Member States' Responsible Authorities under the following MRAs:

MRA	Reference	Publication in Official Journal
MRA EC-Switzerland	Commission Decision 2/2002, Agreement of Annex 1, Chapter 15, Section II	OJ L114/369 of 30.04.2002; OJ L 68/1 of 12.03.2003
MRA EC-Canada	Council Decision 98/566/EC Agreement, Sectoral Annex on GMP, Appendix 2	OJ L 280/3 of 16.10.1998
MRA EC-Australia	Council Decision 98/508/EC Agreement, Sectoral Annex on medicinal products/ GMP, Section II	OJ L 229/1 of 17.08.1998
MRA EC-New Zealand	Council Decision 98/509/EC Agreement, Sectoral Annex on medicinal products/ GMP, Section II	OJ L 229/61 of 17.08.1998
MRA EC-Japan	Council Decision 2001/747/EC Agreement, Sectoral Annex on GMP, Part B	OJ L 284/3 of 29.10.2001

Member State		Responsible authority for human medicinal products	Responsible authority for veterinary medicinal products
Belgium	Name of authority	Direction générale Medicaments / Directoraat-generaal Geneesmiddelen	See responsible authority for human medicinal products
	Street	Eurostation, blok 2 Victor Hortaplein 40 bus 10	
	Postal Code, City	1060 Bruxelles/Brussel	
	Phone	+32-2 524 82 50	
	Fax	+32-2 524 82 57	
	E-Mail		
Czech Republic	Name of authority	State Institute for Drug Control	Institute for State Control of Veterinary Biologicals and Medicaments
	Street	Srobarova 48	Hudcova Street 56a
	Postal Code, City	100 41 Prague 10	621 00 Brno
	Phone	+420 2 7218 5707	+420 2 541 518 201
	Fax	+420 2 7218 5828	+420 2 541 210 026
	E-Mail		

Denmark	Name of authority	The Danish Medicines Agency	See responsible authority for human medicinal products
	Street	Axel Heides Gade 1	
	Postal Code, City	DK-2300 Copenhagen S	
	Phone	+45 44 88 95 95	
	Fax	+45 44 88 95 99	
	E-Mail	dkma@dkma.dk	
Germany	Name of authority	Bundesministerium für Gesundheit und soziale Sicherheit	Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines
	Street	Am Proposthof 78a	Postfach/PO Box
	Postal Code, City	53121 Bonn	63207 Langen
	Phone	+49 228 941 11 43	+49 610 377 10 10
	Fax	+49 228 941 49 59	+49 610 377 12 34
	E-Mail		
Estonia	Name of authority	State Agency of Medicines	See responsible authority for human medicinal products
	Street	19 Ravila Street	
	Postal Code, City	50411 Tartu	
	Phone	+372 7 374 140	
	Fax	+372 7 374 142	
	E-Mail		
Greece	Name of authority	National Organisation for Medicines	See responsible authority for human medicinal products
	Street	Mesogion 284	
	Postal Code, City	15562 Athens	
	Phone	+30 210 650 72 80	
	Fax	+30 210 654 95 91	
	E-Mail		

Spain	Name of authority	Agencia Española de Medicamentos y productos Sanitarios	See responsible authority for human medicinal products
	Street	C/ Alcalá, 56	
	Postal Code, City	28014 Madrid	
	Phone	+34 1 822 52 01/02	
	Fax	+34 1 822 52 43	
	E-Mail		
France	Name of authority	Agence Française de Sécurité Sanitaire des produits de Santé	Agence Nationale du Médicament Vétérinaire
	Street	143Boulevard Anatole France	La Haute Marche-Javené
	Postal Code, City	93200 Saint-Denis	35133 Fougères
	Phone	+33 1 55 87 30 00	+33 2 99 94 78 78
	Fax	+33 1 55 87 30 14	+33 2 99 94 78 99
	E-Mail		
Ireland	Name of authority	Irish Medicines Board	See responsible authority for human medicinal products
	Street	Block A, The Earlsfort Centre, Earlsfort Terrace	
	Postal Code, City	Dublin 2	
	Phone	+353 1 676 49 71	
	Fax	+353 1 676 78 36	
	E-Mail	imb@imb.ie	
Italy	Name of authority	Agenzia Italiana del Farmaco	Ministero della Salute
	Street	Via della Sierra Nevada, 60	Viale della Civiltà Romana 7
	Postal Code, City	00144 Roma	00144 Roma
	Phone	+39 06 59 78 401	+39 06 59 94 42 09
	Fax		+39 06 59 94 42 49
	E-Mail		

Cyprus	Name of authority	The Drugs Council, Pharmaceutical Services (Ministry of Health)	Veterinary Services (Ministry of Agriculture)
	Street	7 Larnakos Avenue	Athalassa
	Postal Code, City	1475 Lefkosia	1417 Nicosia
	Phone	+357 22 40 71 03	+357 22 80 52 00
	Fax	+357 22 40 71 49/+357 22 30 52 55	+357 22 30 52 11
	E-Mail		
Latvia	Name of authority	State Agency of Medicines	Food and Veterinary Service
	Street	15 Jersikas Street	Republikas laukums 2
	Postal Code, City	1003 Riga	LV-1010, Riga
	Phone	+371 70 78 400	+371 7095239
	Fax	+371 70 78 428	+ 371 7322727
	E-Mail		
Lithuania	Name of authority	State Medicines Control Agency	Lithuanian State Inspection on Veterinary Preparations
	Street	Traku str. 14	J. Naujalio g.21b
	Postal Code, City	01132 Vilnius	48332 Kaunas
	Phone	+370 5 263 92 64	+370 37 267 455
	Fax	+370 5 263 92 65	+370 37 361 241
	E-Mail		
Luxembourg	Name of authority	Ministère de la Santé, Division de la Pharmacie et des Médicaments	See responsible authority for human medicinal products
	Street	Villa Louvigny, Allée Marconi	
	Postal Code, City	2120 Luxembourg	
	Phone	+352 47 85 590/93	
	Fax	+352 26 20 01 40 or +352 26 20 01 47	
	E-Mail		

Hungary	Name of authority	National Institute of Pharmacy	Institute for Veterinary Medicinal Products
	Street	H-1051 Budpaest V. Zrinyi u.3	P O Box 318
	Postal Code, City	H-1372 Budapest PO Box 450	Budapest 10, H-1475
	Phone	+361 317 40 44	+361 301 59 79
	Fax	+361 317 14 62	+36 1 301 46 37
	E-Mail		szabados@oai.hu
Malta	Name of authority	Medicines Regulatory Authority	Food and Veterinary Regulatory Division Department of Veterinary Services
	Street	198 rue d'Argens	Albertain
	Postal Code, City	Gzira	Marsa CMR 02
	Phone	+356 234 39 000	+356 21 22 53 63
	Fax	+356 234 39 161	+356 21 23 81 05
	E-Mail		
Netherlands	Name of authority	Ministerie van Volksgezondheid, Welzijn en Sport	See responsible authority for human medicinal products
	Street	Parnassusplein 5, 2511 VX The Hague	
	Postal Code, City	P.O. Box 20350,2500 EJ The Hague	
	Phone	+31 70 340 79 11	
	Fax	+31 70 340 78 34	
	E-Mail		
Austria	Name of authority	Bundesministerium für Gesundheit und Frauen	See responsible authority for human medicinal products
	Street	Radetzkystrasse 2	
	Postal Code, City	1031 Wien	
	Phone	+43 1 711 00 4643	
	Fax	+43 1 713 4404 1530	
	E-Mail		

Poland	Name of authority	The Main Pharmaceutical Inspectorate	General Veterinary Inspectorate
	Street	UL. Długa 38/40	30 Wspolna Street
	Postal Code, City	00-238 Warsaw	00930 Warsaw
	Phone	+48 22 831 21 31	+48 22 623 20 88
	Fax	+48 22 831 02 44	+48 22 623 14 08
	E-Mail	gif@gif.gov.pl	wet@wetgif.gov.pl
Portugal	Name of authority	INFARMED Instituto Nacional da Farmácia e do Medicamento	See responsible authority for human medicinal products
	Street	Parque de Saúde de Lisboa Avenida do Brasil n.º 53	
	Postal Code, City	1749-004 Lisboa	
	Phone	+351 21 798 7260	
	Fax	+351 21 798 7257	
	E-Mail		
Slovenia	Name of authority	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	See responsible authority for human medicinal products
	Street	Mali trg 6	
	Postal Code, City	1000 Ljubljana	
	Phone	+386 1 478 62 40	
	Fax	+386 1 478 62 60	
	E-Mail		
Slovak Republic (Slovakia)	Name of authority	State Institute for Drug Control	Institute for State Control of Veterinary Biologicals and Medicaments
	Street	Kvetna 11	Biovetska 37
	Postal Code, City	82508 Bratislava	94901 Nitra
	Phone	+421 2 5070 1111	+421 376 515 501-3
	Fax	+421 2 555 641 27	+421 376 517 915
	E-Mail		

Finland	Name of authority	National Agency for Medicines	See responsible authority for human medicinal products
	Street	PO Box 55	
	Postal Code, City	00301 Helsinki	
	Phone	+358 9 47 33 41	
	Fax	+358 9 47 33 42 67	
	E-Mail		
Sweden	Name of authority	Medical Products Agency	See responsible authority for human medicinal products
	Street	Dag Hammarkjolds vag 42, Box 26	
	Postal Code, City	75103 Uppsala	
	Phone	+46 18 17 46 00	
	Fax	+46 18 54 85 66	
	E-Mail		
United Kingdom	Name of authority	Medicines and Healthcare products Regulatory Agency	Veterinary Medicines Directorate
	Street	Market Towers, 1 Nine Elms Lane	Woodham Lane, New Haw
	Postal Code, City	London SW8 5NQ	
	Phone	+44 20 70 84 20 00	+44 1932 33 69 11
	Fax	+44 20 70 84 23 53	+44 1932 33 66 18
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