



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2012
EMA/262123/2012 Rev. 1
Product Data Management

Dossier requirements

Members of the Committee for medicinal products for human use (CHMP)

National Competent Authority	Name	CD Rom If Rapporteur/Co-rapporteur CTD format	CD Rom If not Rapporteur/Co-rapporteur CTD format	Dossier Delivery Address
CHMP Chair	Tomas Salmonson	Not Required	Not Required	
CHMP Vice-Chair	Ian Hudson	Not Required	Not Required	
AT representative	Andrea Laslop	2 CD Rom	1 CD Rom Modules 1 and 2	AGES PharmMed Traisengasse 5, A-1200 Vienna, AUSTRIA
AT alternate	Milena Stain	As for the AT representative	Not Required	AGES PharmMed Traisengasse 5, A-1200 Vienna, AUSTRIA
BE representative	Pieter Neels	Contact BE representative in advance	1 CD Rom	Service Public Fédéral Santé Publique, Sécurité de la Chaîne alimentaire et Environnement Victor HORTA Place 40 BP 40 1060 Brussels BELGIUM



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BE alternate	Walter Janssens	As for the BE representative	Not Required	EUROSTATION gebouw, blok2, Victor Hortaplein 40/40, Batiment Eurostation,bloc 2, place Victor Horta, 40/40, B-1060 Brussel Bruxelles- BELGIUM
BG representative	Mila Vlaskovska	2 CD Rom	1 CD Rom Modules 1 and 2	Bulgarian Drug Agency 8, Damyan Gruev str. 1303 Sofia BULGARIA
BG alternate	Lyubina Todorova	As for the BG representative	Not Required	Bulgarian Drug Agency 8, Damyan Gruev str.1303 Sofia BULGARIA
CY representative	Arthur Isseyegh	2 CD Rom	1 CD Rom	Ministry of Health 7 Larnacos Avenue 1475 Lefkosia, Nicosia CYPRUS
CY alternate	Emilia Mavrokordatou	As for the CY representative	Not Required	Ministry of Health 7 Larnacos Avenue 1475 Lefkosia, Nicosia CYPRUS
CZ representative	Ondřej Slanař	2 CD Rom	1 CD Rom	1st Faculty of Medicine, Department of Pharmacology, Albertov 4, 128 00 Praha 2 CZECH REPUBLIC
CZ alternate	Miloslav Salavec	As for the CZ representative	Not Required	Státní ústav pro kontrolu léčiv (SUKL) Šrobárova 48, Praha 10 100 41 CZECH REPUBLIC
DK representative	Jens Heisterberg	4 CD Rom	1 CD Rom	The Danish Medicines Agency Axel Heides Gade 12300 København DENMARK
DK alternate	Jens Ersbøll	As for the DK representative	Not Required	The Danish Medicines Agency Axel Heides Gade 12300 København DENMARK
EE representative	Alar Irs	2 CD Rom	1 CD Rom	State Agency of Medicines Nooruse 1 50411 Tartu Estonia

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EE alternate	Irja Lutsar	As for the EE representative	Not Required	State Agency of Medicines Nooruse 1 50411 Tartu Estonia
FI representative	Outi Mäki-Ikola	2 CD Rom	1 CD Rom	Finnish Medicines Agency P.O.Box 55 Mannerheimintie 103b,FI-00130 Helsinki FINLAND
FI alternate	Janne Komi	As for the FI representative	Not Required	Finnish Medicines Agency P.O.Box 55 Mannerheimintie 103b 00301 Helsinki FINLAND
FR representative	Pierre Demolis	3 CD Rom	1 CD Rom	ANSM 143-147 Bd. Anatole France 93285 Saint Denis Cedex FRANCE
FR alternate	Philippe Lechat	As for the FR representative	Not Required	ANSM 143-147 Bd. Anatole France 93285 Saint Denis Cedex FRANCE
DE representative	Harald Enzmann	3 CD Rom	3 CD Rom	Bundesinstitut für Arzneimittel und Medizinprodukte Kurt-Georg-Kiesinger-Allee 3 53175 Bonn GERMANY
DE alternate	Martina Weise	As for the DE representative	Not Required	Bundesinstitut für Arzneimittel und Medizinprodukte Kurt-Georg-Kiesinger-Allee 3 53175 Bonn GERMANY
GR representative	Catherine Moraiti	1 CD Rom	1 CD Rom Modules 1 and 2	National Organization for Medicines 284 Messogeion Avenue Holargos 155 62 Athens GREECE
GR alternate	Chrysoula Ntaousani	As for the GR representative	Not Required	National Organization for Medicines 284 Messogeion Avenue Holargos 155 62 Athens GREECE

National Competent Authority	Name	CD Rom If Rapporteur/Co-rapporteur CTD format	CD Rom If not Rapporteur/Co-rapporteur CTD format	Dossier Delivery Address
HU representative	Agnes Gyurasics	2 CD Rom	1 CD Rom	National Institute of Pharmacy Zrinyi u. 3 1051Budapest HUNGARY
HU alternate	János Borvendég	As for the HU representative	Not Required	National Institute of Pharmacy Zrinyi u. 3 1051Budapest HUNGARY
IS representative	Kolbeinn Gudmundsson	2CD Rom	1 CD Rom	Lyfjastofnun, Licensing Unit Vínlandsleið 14, IS-113 Reykjavík, ICELAND
IS alternate	Reynir Arngrímsson	As for the IS representative	Not Required	Lyfjastofnun, Licensing Unit Vínlandsleið 14, IS-113 Reykjavík, ICELAND
IR representative	David Lyons	2 CD Rom	1 CD Rom	Receipts and Validation Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 IRELAND
IR alternate	Patrick Salmon	As for the IE representative	Not Required	Receipts and Validation Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 IRELAND
IT representative	Daniela Melchiorri	2 CD Rom	1 CD Rom	AIFA- Agenzia Italiana del Farmaco Via del Tritone, 181 00187 Roma ITALY
IT alternate	Luca Pani	As for the IT representative	Not Required	AIFA- Agenzia Italiana del Farmaco Via del Tritone, 181 00187 Roma ITALY
LV representative	Juris Pokrotnieks	2 CD Rom	1 CD Rom	State Agency of Medicines 15 Jersikas iela, Riga, LV-1003 LATVIA

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LV alternate	Natalja Karpova	As for the LV representative	Not Required	State Agency of Medicines 15 Jersikas iela, Riga, LV-1003 LATVIA
LT representative	Romaldas Mačiulaitis	2 CD Rom	1 CD Rom	State Medicines Control Agency Savanorių, PR 220 3000 Kaunas LITHUANIA
LT alternate	Rugile Pilvinienė	As for the LT representative	Not Required	State Medicines Control Agency Žirmūnų g. 139A LT-0912, Vilnius Lithuania
LU representative	Jacqueline Genoux-Hames	2 CD Rom	1 CD Rom	Division de la Pharmacie et des Médicaments Villa Louvigny Allée Marconi 2120 Luxembourg LUXEMBOURG
LU alternate	Carine de Beaufort	As for the LU representative	Not Required	Centre Hospitalier de Luxembourg, 4, rue Barblé, 1210 Luxembourg, LUXEMBOURG
MT representative	John Joseph Borg	2 CD Rom	1 CD Rom	Medicines Authority 203, Level 3, rue D'Argens GZR 1368 Gzira MALTA
MT alternate	Patricia Vella Bonanno	As for the MT representative	Not Required	Medicines Authority 203, Level 3, rue D'Argens GZR 1368 Gzira MALTA
NL representative	Barbara van Zwieten-Boot	1 DVD or CD Rom	1 DVD or CD Rom	Graadt van Roggenweg 500 3531 AH Utrecht The Netherlands
NL alternate	Pieter de Graeff	As for the NL representative	Not Required	Graadt van Roggenweg 500 3531 AH Utrecht The Netherlands
NO representative	Karsten Bruins Slot	3 CD Rom (module 1-5) 1 CD(module 1-2)	1 CD Rom	Statens legemiddelverk Sven Oftedals vei 6 N-0950 Oslo NORWAY

National Competent Authority	Name	CD Rom If Rapporteur/Co-rapporteur CTD format	CD Rom If not Rapporteur/Co-rapporteur CTD format	Dossier Delivery Address
NO alternate	Ingunn Hagen Westgaard	As for the NO representative	Not Required	Postbox 63, Kalbakken, N-0901 Oslo, NORWAY
PL representative	Piotr Fiedor	6 CD Rom	2 CD Rom	Office for Medicinal Products, Medical Devices and Biocides 41 Zabkowska Str. 03-736 Warsaw POLAND
PL alternate	Kinga Borowicz	As for the PL representative	Not Required	The Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology Roentgena 5 02-781 Warsaw POLAND
PT representative	Bruno Sepodes	2 CD Rom	1 CD Rom	INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., Parque de Saúde de Lisboa, Avenida do Brasil, 53, 1749-004 Lisboa, PORTUGAL
PT alternate	Dinah Duarte	As for the PT representative	Not Required	INFARMED Parque de Saúde de Lisboa Av. Do Brasil, 53 1749-004 Lisboa PORTUGAL
RO representative	Nela Vilceanu	2 CD Rom	1 CD Rom	National Medicines Agency Str. Aviator Sănătescu 48 Sector 1 71324 Bucharest ROMANIA
RO alternate	Dana Gabriela Marin	As for the RO representative	Not Required	National Medicines Agency Str. Aviator Sănătescu 48 Sector 1 71324 Bucharest ROMANIA

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SK representative	Jan Mazag	2 CD Rom	1 CD-Rom with Modules 1 and 2	State Institute of Drug Control Kvetna 11 82508 Bratislava 26 SLOVAK REPUBLIC
SK alternate	Vlasta Kákošová	As for the SK representative	Not Required	State Institute of Drug Control Kvetna 11 82508 Bratislava 26 SLOVAK REPUBLIC
SI representative	Stanislav Primožič	2 CD Rom	1 CD Rom	Agency for Medicinal Products and Medical Devices Ptujška ulica 21 1000 Ljubljana SLOVENIA
SI alternate	Nevenka Trsinar	As for the SI representative	Not Required	Agency for Medicinal Products and Medical Devices Ptujška ulica 21 1000 Ljubljana SLOVENIA
ES representative	Concepcion Prieto Yerro	5 CD Rom	1 CD Rom	Agencia Española del Medicamento y Productos Sanitarios Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1 28022 Madrid SPAIN
ES alternate	Arantxa Sancho-Lopez	As for the ES representative	Not Required	Agencia Española de Medicamentos y Productos Sanitarios, Clinical Pharmacology Department Parque Empresarial Las Mercedes , Edificio 8 , C/Campezo 1, 28022 Madrid, SPAIN
SE representative	Kristina Dunder	1 CD Rom	1 CD Rom	Medical Products Agency Dag Hammarskjölds väg 42, P.O.Box 26 751 03 Uppsala SWEDEN

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*SE alternate	Bengt Ljungberg	Not Required	Not Required	Medical Products Agency Dag Hammarskjölds väg 42, 75183 Uppsala, SWEDEN
UK representative	Ian Hudson	1 CD Rom	1 CD Rom	Medicines and Healthcare products Regulatory Agency 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ UK
UK alternate	Rafe Suvarna	As for the UK representative	Not Required	Medicines and Healthcare products Regulatory Agency 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ UK

Co-Opted Members of the CHMP				
Jan Mueller-Berghaus	2 CD Rom	1 CD Rom	Paul-Ehrlich-Institute Paul-Ehrlich Str. 51-59 63225 Langen GERMANY	
Hubert Leufkens	Not Required	Not Required	Chairman College ter Beoordeling van Geneesmiddelen Postbus 16229 2500 BE Den Haag NETHERLANDS	
Jean-Louis Robert	2 CD Rom	1 CD Rom	Laboratoire Nationale de Santé Service du Contrôle des Médicaments 1A Rue A. Lumière, bp 1102 1011 Luxembourg LUXEMBOURG	
Sol Ruiz	2 CD Rom	1 CD Rom	Agencia Española del Medicamento y Productos Sanitarios Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1 28022 Madrid SPAIN	
Robert James Hemmings	1 CD Rom	Not Required	Medicines and Healthcare products Regulatory Agency 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ UK	

*** Update made on 14 December
2012**