



Distribution Requirements and Address Lists for Periodic Safety Update Reports (PSURs)
(Annex 6.2 of Volume 9A of the Rules Governing Medicinal Products in the EU)

Note: CD-ROM means PDF + WORD format (i.e. two formats should be submitted).

Abbreviations: EEA - European Economic Area; CAP - centrally authorised product; MRP/DCP - product authorised through the mutual or decentralised procedures; NAP - purely nationally authorised product; RMS - Reference Member State; P-RMS - PSUR-assessing Reference Member State; CMS - Concerned Member State; MAH - Marketing Authorisation Holder

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Austria	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 or PAPER No of copies: 1	CD-ROM No of copies: 1 or PAPER No of copies: 1	CD-ROM No of copies: 1 or PAPER No of copies: 1	Bundesamt für Sicherheit im Gesundheitswesen AGES PharmMed Institut Pharmakovigilanz Schirchgasse 9 1030 WIEN AUSTRIA

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Belgium	CD-ROM with paper submission letter No of copies: 1	CD-ROM with paper submission letter No of copies: 2	CD-ROM with paper submission letter No of copies: 2 PAPER No of copies: 0	CD-ROM with paper submission letter No of copies: 1 PAPER No of copies: 0	CD-ROM with paper submission letter No of copies: 2 PAPER No of copies: 0	Federal Agency for Medicines and Health Products Belgian Centre for Pharmacovigilance Eurostation II Office 8D383 Victor Horta place, 40/40 1060 BRUSSEL/BRUXELLES BELGIUM <u>Notes:</u> MAHs are encouraged to use e-mail for files < 2 Mb or Eudralink for files < 40 Mb (address: PSURH@fagg-afmps.be). For more information on the e-submission of PSURs: Circular Letter No. 476 on www.fagg-afmps.be .
Bulgaria	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Bulgarian Drug Agency 26, Yanko Sakazov Blvd. 1504 SOFIA BULGARIA

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Cyprus	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Registrar Drugs Council Pharmaceutical Services Ministry of Health 1475 NICOSIA CYPRUS
Czech Republic	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Pharmacovigilance Unit State Institute for Drug Control Srobarova 48 100 41 PRAHA 10 CZECH REPUBLIC
Denmark	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 1	Danish Medicines Agency Consumer Safety Division Axel Heides Gade 1 2300 KØBENHAVN S DENMARK
Estonia	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Bureau of Pharmacovigilance State Agency of Medicines Nooruse Street 1 50411 TARTU ESTONIA

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Finland	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Attn.: Department of Safety and Drug Information National Agency for Medicines P.O. Box 55 00301 HELSINKI FINLAND
France	CD-ROM No of copies: 2	CD-ROM No of copies: 0	CD-ROM No of copies: 2 PAPER No of copies: 2	CD-ROM No of copies: 2 PAPER No of copies: 2	CD-ROM No of copies: 2 PAPER No of copies: 2	Agence Française de Sécurité Sanitaire des Produits de Santé DEMEB / DORIS / URAMM 143-147, Boulevard Anatole France 93285 SAINT-DENIS CEDEX FRANCE

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Germany	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	Bundesinstitut für Arzneimittel und Medizinprodukte Kurt-Georg-Kiesinger Allee 3 53175 BONN GERMANY <u>For vaccines and blood and plasma-derived medicinal products, recombinant coagulation factors and monoclonal antibodies:</u> Paul-Ehrlich-Institut Attn.: Referat S1 / Drug Safety Paul-Ehrlich-Strasse 51-59 63225 LANGEN GERMANY
Greece	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Ministry of Health, Welfare National Organization for Medicines Department of Pharmaceutical Studies Adverse Drug Reactions Section 284 Mesogion Av. 15562 HOLARGOS GREECE

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Hungary	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	National Institute of Pharmacy Department of Pharmacovigilance Zrínyi u. 3 1051 BUDAPEST HUNGARY
Ireland	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	Receipts & Validation Unit Irish Medicines Board Earlsfort Centre Earlsfort Terrace DUBLIN 2 IRELAND
Italy	CD-ROM No of copies: 2	CD-ROM No of copies: 0	CD-ROM No of copies: 2 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 2 PAPER No of copies: 0	Agenzia Italiana del Farmaco Via di Sierra Nevada 60 00144 ROMA ITALY
Latvia	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	State Agency of Medicines of Latvia 15, Jersikas St RIGA 1003 LATVIA

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Lithuania	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	State Medicines Control Agency Medicines Safety and Information Unit Traku Street 9/1 01132 VILNIUS LITHUANIA
Luxembourg	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Division de la Pharmacie et des Médicaments Villa Louvigny Allee Marconi 2120 LUXEMBOURG LUXEMBOURG

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Malta	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 1	<u>6-monthly, annual and interim PSURs:</u> Attn. of Pharmacovigilance Staff Member Post-Licensing Directorate Medicines Authority 198, Rue D'Argens GZIRA GZR 03 MALTA <u>First and subsequent renewal PSURs:</u> Post-Licensing Directorate Medicines Authority 198, Rue D'Argens GZIRA GZR 03 MALTA
Netherlands	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Medicines Evaluation Board (MEB) Kalvermarkt 53 P.O. Box 16229 2500 BE DEN HAAG THE NETHERLANDS

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Poland	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Pharmacovigilance Unit 41 Zabkowska Street 03 736 WARSZAWA POLAND
Portugal	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Directorate of Risk Management of Medicines INFARMED, I.P. Parque de Saúde de Lisboa Av. do Brasil, 53 1749 – 004 LISBOA PORTUGAL
Romania	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	National Medicines Agency Str. Aviator Sanatescu, Nr. 48, Sector 1 BUCURESTI ROMANIA

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Slovak Republic	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 2	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	State Institute for Drug Control Section for Pharmacovigilance and Clinical Trials Kvetná 11 825 08 BRATISLAVA 26 SLOVAK REPUBLIC
Slovenia	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia Einspielerjeva 6 1000 LJUBLJANA SLOVENIA
Spain	CD-ROM No of copies: 1	CD-ROM No of copies: 2	CD-ROM No of copies: 2	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 2 PAPER No of copies: 0	División de Farmacoepidemiología y Farmacovigilancia Agencia Española del Medicamentos y Productos Sanitarios Calle Campezo, 1 Edificio 8 - 3 Parque Empresarial las Mercedes 28022 MADRID SPAIN <i>Note:</i> PSURs to be submitted with cover detailed in Circular 15/2002.

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Sweden	CD-ROM No of copies: 1	CD-ROM No of copies: 3	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	Medical Products Agency PO Box 26 75103 UPPSALA SWEDEN
United Kingdom	CD-ROM No of copies: 1	CD-ROM No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Medicines and Healthcare products Regulatory Agency Information Processing Unit 1, Nine Elms Lane LONDON SW8 5NQ UNITED KINGDOM
Iceland	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Icelandic Medicines Control Agency Eidistorgi 13-15 P.O. Box 180 172 SELTJANARNES ICELAND
Liechtenstein	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Amt für Gesundheit Äulestrasse 51 9490 VADUZ LIECHTENSTEIN

Member State/ EEA Country/ Agency	PSUR submission requirements					Addressee(s)
	CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
	Always	In addition if Rapporteur	(P-)RMS	CMS		
Norway	CD-ROM No of copies: 1	CD-ROM No of copies: 0	CD-ROM No of copies: 0 PAPER No of copies: 1	CD-ROM No of copies: 0 PAPER No of copies: 1	CD-ROM No of copies: 0 PAPER No of copies: 1	Norwegian Medicines Agency Sven Oftedals vei 8 0950 OSLO NORWAY
EMEA Secretariat	Electronic Submission, see EMEA Post-Authorisation Procedural Advice website: http://www.emea.europa.eu/htms/human/postguidance/index.htm					