EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 August 2014
EMA/413951/2012 – Rev.8
Procedure Management and Business Support

Important Note: This document is superseded by the guidance document "***Requirements on Submissions for Periodic safety update reports (PSUR) to National Competent Authorities (NCAs) for products authorised via National Procedures, MRP and DCP (NAPs)***" available in the link**:** http://www.hma.eu/314.html.

National Competent Authorities (NCAs) and European Medicines Agency (EMA) requirements for submission of PSUR during the transitional period

The Article 2 (7) of Directive 2001/83/EC as amended specifies that "*Until the Agency can ensure the functionalities agreed for the repository of the periodic safety update reports, the marketing authorisation holders shall submit the periodic safety reports to all Member States in which the medicinal product has been authorised*." This document aims at making publicly available the submission requirements of all Member States as regard Periodic Safety Update Reports (PSURs) during the transitional period, starting from July 2012 until 12 months after the functionalities of the PSUR repository have been established and announced by the European Medicines Agency (EMA). Therefore, until centralised submission to the repository, PSURs will be sent directly to the National Competent Authorities (NCAs) of the Member States where the products/substances are authorised.

In February 2012, the EMA published a plan for the implementation of the new Pharmacovigilance Legislation requirements. Following the December 2012 EMA Management Board meeting, the EU single assessment of substances contained in both centrally and nationally authorised products (CAPs and NAPs) with involvement of the PRAC will start with the substances with a Data Lock Point in April 2013, corresponding to the entry into force of the list of Union reference dates and frequency of submission of PSUR, also called "EURD list". The centralised submission of PSURs is a key element for the optimisation of the functioning of the EU single assessment procedure. As a consequence, MAHs of CAPs and NAPs subject to an EU single assessment should submit their **PSURs to all the PRAC and CHMP members representing the National Competent Authorities (NCAs) of the countries**

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
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Send a question via our website www.ema.europa.eu/contact

where the medicinal products have been authorised, to the PRAC rapporteur of the procedure, and to the EMA. For the details regarding submission requirements, reference should be made to the table below. For the list of PRAC and CHMP members, please refer to the "Dossier requirements for Centrally Authorised Products (CAPs)".

Note: For medicinal products with documentation previously submitted in eCTD format, PSURs should also be presented as a separate eCTD sequence in the respective eCTD submission of the concerned product. For the other products, PSURs may be required to be submitted in Non-eCTD electronic Submissions (NeeS):

http://esubmission.emea.europa.eu/tiges/docs/NeeS%20eGuidance%20Document%20v3%200_2011_TIGes%20adopted%20for%20publication.pdf

http://esubmission.emea.europa.eu/tiges/tigesdocuments.html

Abbreviations: EEA - European Economic Area; CAP - centrally authorised product; MRP/DCP - product authorised through the mutual or decentralised procedures; NAP - nationally authorised products including MRP and DCP; RMS - Reference Member State; P-RMS - PSUR-assessing Reference Member State; CMS - Concerned Member State; MAH - Marketing Authorisation Holder; CHMP - Committee for Medicinal Products for Human Use; PRAC - Pharmacovigilance Risk Assessment Committee

Member State / EEA Country / Agency	PSUR submission requirements				Addressee(s) and additional notes
	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Austria	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper or sent electronically with attached secure electronic signature	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper or sent electronically with attached secure electronic signature	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper or sent electronically with attached secure electronic signature	Bundesamt für Sicherheit im Gesundheitswesen / AGES Medizinmarktaufsicht; Institut Pharmakovigilanz Traisengasse 5 1200 Wien

Member State / EEA Country / Agency	PSUR submission requirements				Addressee(s) and additional notes
	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Belgium	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies : 2 Signed cover letter in Paper	1 CD-ROM Number of copies : 1 Signed cover letter in Paper	1 CD-ROM Number of copies : 1 Signed cover letter in Paper	Federal Agency for Medicines and Health Products - Belgian Centre for Pharmacovigilance Eurostation II - Office 8D383 Victor Horta place, 40/40 1060 BRUSSEL/BRUXELLES BELGIUM Note: 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 http://www.fagg-afmps.be
Bulgaria	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	2 CD-ROMs including: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper	Bulgarian Drug Agency 8, Damyan Gruev, Str. 1303 Sofia Bulgaria

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Croatia	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (PDF) : 1	1 CD-ROM Number of copies (PDF) : 1	1 CD-ROM Number of copies (PDF) : 1	Agencija za lijekove i medicinske proizvode – HALMED Ulica Roberta Frangeša Mihanovića 9 10000 Zagreb Croatia
Cyprus	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies: 1 PAPER Number of copies: 1	1 CD-ROM Number of copies: 1	1 CD-ROM Number of copies: 1	Registrar Drugs Council Pharmaceutical Services Ministry of Health 1475 NICOSIA CYPRUS
Czech Republic	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (PDF): 1 Number of copies (Word): 1 PAPER Number of copies (paper): 1	1 CD-ROM Number of copies (PDF): 1 Number of copies (Word): 1	1 CD-ROM Number of copies (PDF): 1 Number of copies (Word): 1	State Institute for Drug Control Šrobárova 48 100 41 Praha 10 CZECH REPUBLIC

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		When the NCA is (P)RMS	When the NCA is CMS		
Denmark	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	The Danish Health and Medicines Authority Division of Pharmacovigilance and Medical Devices Axel Heides Gade 1, DK-2300 København S DENMARK
Estonia	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	E-mail (see notes) or CESP	E-mail (see notes) or CESP	E-mail (see notes) or CESP	CAP: psurCAP@ravimiamet.ee MRP/DCP/NAP/ PSUR WS P-RMS: documentation@ravimiamet.ee Should the size limit of electronic transmission be exceeded, 1 copy of a CD-ROM should be sent to State Agency of Medicines, Nooruse 1, Tartu 50411, Estonia

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Finland	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1 PAPER Number of copies : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	Finnish Medicines Agency Fimea Pharmacovigilance P.O.Box 55 FI-00034 FIMEA FINLAND
France	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	If submission in eCTD or NeeS: 1 CD-ROM or DVD Number of copies (PDF version 1.4 with no restriction) : 1 If PAPER submission: Number of copies : 2 + 2 CD-ROMs or DVDs containing PDF version 1.4 with no restriction	If submission in eCTD or NeeS: 1 CD-ROM or DVD Number of copies (PDF version 1.4 with no restriction) : 1 If PAPER submission: Number of copies : 2 + 2 CD-ROMs or DVDs containing PDF version 1.4 with no restriction	If submission in eCTD or NeeS: 1 CD-ROM or DVD Number of copies (PDF version 1.4 with no restriction) : 1 If PAPER submission: Number of copies : 2 + 2 CD-ROMs or DVDs containing PDF version 1.4 with no restriction	Electronic submission: ANSM / DEMEB / DORIS/ Unité RECEVABILITE AMM Soumission électronique (eCTD/EU-Nees) 143-147 BOULEVARD ANATOLE FRANCE F-93285 SAINT –DENIS CEDEX Paper submission : ANSM / DEMEB / DORIS/ Unité RECEVABILITE AMM 143-147 BOULEVARD ANATOLE FRANCE F-93285 SAINT –DENIS CEDEX Note: Once the electronic submission is used, the switch to paper is no more accepted.

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		When the NCA is (P)RMS	When the NCA is CMS		
Germany (BfArM)	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	2 CD-ROMs Number of copies (PDF) : 1	2 CD-ROMs Number of copies (PDF) : 1	National Procedure: 2 CD-ROMs Number of copies (PDF) : 1 MR/DC Procedures: 2 CD-ROMs Number of copies (PDF) : 1	Federal Institute for Drugs and Medical Devices (BfArM) - Pharmacovigilance – PSUR Kurt-Georg-Kiesinger-Allee 3 D-53175 Bonn Germany Notes: BfArM accepts pre-checked CDs/DVDs in eCTD format (preferred) or NeeS.
Germany (Paul Ehrlich Institut)	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1 PAPER Number of copies : 1	Paul-Ehrlich-Institut (PEI) Paul-Ehrlich-Strasse 51-59 63225 Langen (Hessen) Germany Notes: PEI accepts pre-checked CDs/DVDs in eCTD format (preferred). In these cases, please submit a duplicate copy of the CD/DVD in word format

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		When the NCA is (P)RMS	When the NCA is CMS		
Greece	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	National Organization for Medicines Administration Unit General Secretariat (Protocol) Dept. 284, Mesogion Ave 15562 Holargos Greece
Hungary	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	Via EMAIL Number of copies (PDF) : 1 Number of copies (Word) : 1	Via EMAIL Number of copies (PDF) : 1	Via EMAIL Number of copies (PDF) : 1	National Institute of Pharmacy Zrinyi u 3 H-1051 Budapest Hungary Email: adr.box@gyemszi.hu Should the size limit of electronic transmission be exceeded, 1 copy of a CD-ROM should be sent to National Institute of Pharmacy, with a simultaneous notification of the submission in e-mail.

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Ireland	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	Receipts &Validation Department Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace DUBLIN 2, IRELAND
Italy	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	2 CD-ROMs including: Number of copies (PDF) : 1 Number of copies (Word) : 1	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1	2 CD-ROMs including: Number of copies (PDF) : 1 Number of copies (Word) : 1	Agenzia Italiana del Farmaco Via del Tritone 181 00187 ROMA ITALY Note: for centralised procedures, indicate the EMA procedure number
Latvia	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM or EMAIL with attached secure electronic signature: Number of copies (PDF) : 1 Number of copies (Word) : 1 PAPER Number of copies : 1 Signed cover letter in Paper or sent electronically with attached secure electronic signature	1 CD-ROM or EMAIL with attached secure electronic signature: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper or sent electronically with attached secure electronic signature	1 CD-ROM or EMAIL with attached secure electronic signature: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper or sent electronically with attached secure electronic signature	State Agency of Medicines of Latvia 15, Jersikas St RIGA LV-1003 Latvia Email for electronic submissions of PSUR and cover letters : info@zva.gov.lv

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Lithuania	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 EMAIL with attached secure electronic signature: Number of copies (PDF) : 1	1 CD-ROM Number of copies (PDF) : 1	EMAIL with attached secure electronic signature: Number of copies (PDF) : 1	FOR NAP: State Medicines Control Agency, Zirmunu 139A, LT-09120, Vilnius Lithuania Electronic submissions: psur@vvkt.lt
Luxembourg	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	Awaiting requirements	Awaiting requirements	Awaiting requirements	Division de la Pharmacie et des Médicaments Villa Louvigny Allée Marconi 2120 Luxembourg LUXEMBOURG
Malta	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1 PAPER Number of copies : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	Medicines Authority 203/Level 3 Rue D'argens Gzira GZR 1368 Malta

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		When the NCA is (P)RMS	When the NCA is CMS		
Netherlands	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	By CESP or 1 CD-ROM or DVD Number of copies (PDF) : 1 Originally signed cover letter in Paper	By CESP or 1 CD-ROM or DVD Number of copies (PDF) : 1 Originally signed cover letter in Paper	By CESP Or 1 CD-ROM or DVD Number of copies (PDF) : 1 Originally signed cover letter in Paper	Medicines Evaluation Board P.O. Box 8275 3503 RG Utrecht The Netherlands Note: MAHs are encouraged to use CESP (http://cesp.hma.eu/Home)
Poland	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper	1 CD-ROM: Number of copies (PDF) : 1 Number of copies (Word) : 1 Signed cover letter in Paper	The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, 41 Ząbkowska Street, 03-736 Warsaw, Poland Note: The Office for Registration accepts pre-checked CDs /DVDs in eCTD format (preferred) or NeeS format.

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Portugal	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (PDF) : 1 Signed cover letter in Paper	1 CD-ROM Number of copies (PDF) : 1 Signed cover letter in Paper	1 CD-ROM Number of copies (PDF) : 1 Signed cover letter in Paper	INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. Parque de Saúde de Lisboa - Avenida do Brasil, 53 1749-004 Lisboa - Portugal Note: Submission of PSURs in Word format might be requested during the assessment if considered necessary.
Romania	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1 PAPER Number of copies : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	National Agency for Medicines and Medical Devices Str. Aviator Sănătescu, Nr. 48, Sector 1 011478 BUCURESTI ROMANIA Email: psur@anmdm.ro
Slovak Republic	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1 PAPER Number of copies : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	State Institute for Drug Control Section of Drug Safety and Clinical Trials Kvetná 11 825 08 Bratislava 26 Slovak Republic

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Slovenia	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (PDF) : 1	1 CD-ROM Number of copies (Word) : 1	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia Ptujska ulica 21 1000 Ljubljana SLOVENIA
Spain	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	SUBMISSION ON LINE Number of copies (Rar or Zip format) : 1 Cover letter in Word or PDF	SUBMISSION ON LINE Number of copies (Rar or Zip format) : 1 Cover letter in Word or PDF	SUBMISSION ON LINE Number of copies (Rar or Zip format) : 1 Cover letter in Word or PDF	Link to use for submission: https://enviotelematico.aemps.es/enviotelematico/psur/solicitud.do Companies **with** valid Spanish digital certificate: To get a password and username, the Company should send an email to: psur@aemps.es, specifying the Company name, address, a person contact name and email. Companies **without** a valid Spanish digital Certificate: to get access to the application, the Company should contact psur@aemps.es. When applicable, a separate URL will be provided. In both cases, the Company should send the completed

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
					Notice to Applicant v9 (not lower)
Sweden	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM or EMAIL Number of copies (PDF version 1.4-1.7) : 1 Number of copies (Word) : 1	1 CD-ROM or EMAIL Number of copies (PDF version 1.4-1.7) : 1 Number of copies (Word) : 1	1 CD-ROM or EMAIL Number of copies (PDF version 1.4-1.7) : 1 Number of copies (Word) : 1	Medical Products Agency, Dag Hammarskjölds väg 42, PO Box 26, 75103 UPPSALA, SWEDEN. Email: ric@mpa.se
United Kingdom	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM or Email or via the MHRA portal Number of copies (PDF) : 1	1 CD-ROM or Email or via the MHRA portal Number of copies (PDF) : 1	1 CD-ROM or Email or via the MHRA portal Number of copies (PDF) : 1	Regulatory Agency Information Processing Unit 151, Buckingham Palace Road LONDON SW1W 9SZ UNITED KINGDOM
Iceland	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	1 CD-ROM Number of copies (Word) : 1	Lyfjastofnun, Licensing Unit Vínlandsleið 14 IS-113 Reykjavík ICELAND Email: ima@ima.is
Liechtens-tein	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	Not applicable	Not applicable (see Agreements with Austria	1 CD-ROM Number of copies : 1	Amt für Gesundheit, Aeulestrasse 51, 9490 Vaduz, Liechtenstein Email: pharminfo@ag.llv.li

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	CAP	NAP (including MRP/DCP) in PSUR Work Sharing		NAP outside the Work Sharing following national procedures or subject to an EU single assessment	
		When the NCA is (P)RMS	When the NCA is CMS		
Norway	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012 In addition to the above, PSURs can be submitted through CESP.	1 CD-ROM or EMAIL Number of copies (Word) : 1 In addition to the above, PSURs can be submitted through CESP.	1 CD-ROM or EMAIL Number of copies (Word) : 1 In addition to the above, PSURs can be submitted through CESP.	1 CD-ROM or EMAIL Number of copies (Word) : 1 In addition to the above, PSURs can be submitted through CESP.	Norwegian Medicines Agency, Box 63, Kaldbakken, 0901 Oslo, Norway Email: post@noma.no
European Medicines Agency Secretariat	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	PSURs should not be submitted to the EMA until further notice	PSURs should not be submitted to the EMA until further notice	NAP following national procedures: PSURs should not be submitted to the EMA until further notice NAP subject to an EU single assessment: eCTD or NeeS format via the esubmission gateway or webclient.	European Medicines Agency esubmission gateway or webclient For registration : https://esubregistration.ema.europa.eu/registration/ Webclient access: http://pgateway.ema.europa.eu

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		When the NCA is (P)RMS	When the NCA is CMS		
PRAC Independent Scientific experts and CHMP Co-Opted Members	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	PSURs should not be submitted until further notice	PSURs should not be submitted until further notice	For NAPs outside the Work Sharing subject to an EU single assessment: See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012	See "*Dossier requirements for Centrally Authorised Products (CAPs)*", EMA/497021/2012