



SOP/V/4023 – Annex I  
January 2019  
Veterinary Medicines Division

## Standard operating procedure for management of periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products: Annex I – contact details of national competent authorities (NCAs) for PSUR submission

PSURs for centrally authorised products (CAPs) should be submitted via the eSubmission gateway to the Agency and all NCAs. Do not submit any additional copies of CAP submissions directly to the NCAs on CD/DVD or via the [Common European Submission Portal \(CESP\)](#). As previously agreed by the Committee for Medicinal Products for Veterinary Use (CVMP) Pharmacovigilance Working Party (PhVPW-V), for ease of reference, details for submission of non-CAP PSURs are included as follows:

<p>Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH Austrian Agency for Health and Food Safety Traisengasse 5 1200 Wien <b>AUSTRIA</b></p> <p><i>All non-CAP PSURs should be sent via CESP. Otherwise Eudralink<sup>1</sup> submission of PSURs should be sent to: <a href="mailto:basg-v-phv@basg.gv.at">basg-v-phv@basg.gv.at</a></i></p>	<p>Federal Agency for Medicines and Health Products Eurostation bloc II Place Victor Horta 40, bte 40 1060 Bruxelles <b>BELGIUM</b> Fax: +32 2 528 41 36</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:psurv@fagg-afmps.be">psurv@fagg-afmps.be</a> PSURs may also be sent via CESP.</i></p>
<p>Bulgarian Food Safety Agency Control of Veterinary Medicinal Products 7, Shose Bankya Str 1331 Sofia <b>BULGARIA</b> Fax: +359 2 425 06 35</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:s_branchev@itp.bg">s_branchev@itp.bg</a></i></p>	<p>Faculty of Veterinary Medicine University of Zagreb Department of Pharmacology and Toxicology Heinzlova 55, 10000 Zagreb <b>CROATIA</b> Fax: + 385 1 2390 159</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:psur@vef.hr">psur@vef.hr</a></i></p>

<sup>1</sup> Eudralink package expiry: please ensure that Eudralink packages are available for at least 45 days



<p>Institute for State Control of Veterinary Biologicals and Medicines Pharmacovigilance Dpt. Hudcova 56a 621 00 Brno-Medlánky <b>CZECH REPUBLIC</b> Fax: +420 541 210 026</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:adr@uskvbl.cz">adr@uskvbl.cz</a></i></p>	<p>Ministry of Agriculture, Rural Development and Environment Veterinary Services 1417 Nicosia <b>CYPRUS</b> Fax: +357 22 8051 22</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:pharmacovigilance@vs.moa.gov.cy">pharmacovigilance@vs.moa.gov.cy</a> PSURs can also be submitted via CESP.</i></p>
<p>Danish Medicines Agency Veterinary Medicines Evaluation Lægemiddelstyrelsen Veterinaermedicinsk Evaluering Axel Heides Gade 1 2300 København S <b>DENMARK</b> T +45 44 88 95 95</p> <p><i>All non-CAP PSURs should be sent via CESP or Eudralink<sup>1</sup> submission of PSURs to: <a href="mailto:DK-VET@dkma.dk">DK-VET@dkma.dk</a></i></p>	<p>Ravimiamet State Agency of Medicines Department of Marketing Authorisations Nooruse 1 50411 Tartu <b>ESTONIA</b> Fax: +372 7 37 41 42</p> <p><i>All non-CAP PSURs should be sent via CESP. Otherwise Eudralink<sup>1</sup> submission of PSURs should be sent to: <a href="mailto:documentation@ravimiamet.ee">documentation@ravimiamet.ee</a></i></p>
<p>Dr Helen Adam-Amenta National Organisation for Medicines Veterinary Section 284 Mesogion Avenue Holargos 15562 Athens <b>GREECE</b> Fax: +30 21 06 53 75 91</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:psurvet@eof.gr">psurvet@eof.gr</a></i></p>	<p>FIMEA – Finnish Medicines Agency Veterinary Pharmacovigilance P.O. Box 55 FI-00034 FIMEA <b>FINLAND</b></p> <p><i>Non-CAP PSURs should be submitted via CESP or CD/DVD.</i></p>

<p>Secrétariat pharmacovigilance  Agence Française de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES)  Agence Nationale du Médicament Vétérinaire  8 rue Claude Bourgelat  Parc d'activités de la Grande Marche-Javené  CS 70611  35306 Fougères  <b>FRANCE</b>  Fax: +33 2 9994 6671</p> <p><i>All non-CAP PSURs should be sent via CESP. Otherwise Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to : <a href="mailto:secphv@anses.fr">secphv@anses.fr</a></i></p>	<p><u><i>For Immunological Products</i></u>  Paul-Ehrlich-Institut  Paul-Ehrlich-Straße 51-59  63225 Langen  <b>GERMANY</b>  Fax: +49 6103 771279</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:vetmittelsicherheit@pei.de">vetmittelsicherheit@pei.de</a></i></p>
<p><u><i>For Pharmaceutical Products</i></u>  Bundesamt für Verbraucherschutz und Lebensmittelsicherheit  Abteilung 3  Mauerstr. 39-42  10117 Berlin  <b>GERMANY</b>  Fax: +49 3018 444 89999</p> <p><i>Non-CAP PSURs should be submitted via CESP and alternatively via Eudralink<sup>1</sup> to: <a href="mailto:PSUR@bvl.bund.de">PSUR@bvl.bund.de</a></i></p>	<p>National Food Chain Safety Office  Directorate of Veterinary Medicinal Products  Szállás Utca 8  1107 Budapest  <b>HUNGARY</b>  Fax: +36 1 262 28 39</p> <p><i>Electronic submission of non-CAP PSURs should be sent via CESP or Eudralink<sup>1</sup> to <a href="mailto:E-Pharmacovigilance@nebih.gov.hu">E-Pharmacovigilance@nebih.gov.hu</a></i></p>
<p>Icelandic Medicines Agency  Vínlandsleið 14  IS-113 Reykjavík  <b>ICELAND</b>  Fax: +354 561 21 70</p> <p><i>Non-CAP PSURs should preferably be submitted via CESP or less preferably on CD/DVD – but not via Eudralink or e-mail.</i></p>	<p>Ministry of Health  Office 4 – DGSAF  Via G. Ribotta, 5  00144 Roma  <b>ITALY</b>  Fax: +39 06 59 94 69 49</p> <p><i>All PSURs should be preferably sent via CESP. Eudralink<sup>1</sup> submission of non-CAP PSURs may be sent to: <a href="mailto:farmacovigilanzavet@sanita.it">farmacovigilanzavet@sanita.it</a></i></p>

<sup>1</sup> Eudralink package expiry: please ensure that Eudralink packages are available for at least 45 days

<p>Receipts and Validation Department Health Products Regulatory Authority Earlsfort Centre; Earlsfort Terrace Dublin 2 <b>IRELAND</b> Fax: +353 1 676 78 36</p> <p><i>Non-CAP PSURs should preferably be submitted via CESP, or alternatively via Eudralink<sup>1</sup> to: <a href="mailto:submissions@hpra.ie">submissions@hpra.ie</a></i></p>	<p>Food and Veterinary Service Peldu street 30 Riga LV-1050 <b>LATVIA</b></p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:vzr@pvd.gov.lv">vzr@pvd.gov.lv</a> or via CESP.</i></p>
<p>National Food and Veterinary Risk Assessment Institute Veterinary Medicines and Biocides Assessment Unit J.Naujalis g. 21b 48332 Kaunas 26 <b>LITHUANIA</b> Fax: +370 37 406820</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:psur@nmvrvi.lt">psur@nmvrvi.lt</a></i></p>	<p>Mr Marc Wirtor Direction de la Santé Division de la Pharmacie et des Médicaments Villa Louvigny, Parc de la Ville Allée Marconi 2120 Luxembourg <b>LUXEMBOURG</b> Fax: +352 478 50527</p> <p><i>Please contact the above NCA concerning Eudralink<sup>1</sup> submission of non-CAP PSURs.</i></p>
<p>Mr Kenneth Mifsud Food and Veterinary Division Abattoir Square Alberttown CMR 02 Marsa <b>MALTA</b> Fax: +356 21 23 81 05</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:Godwin.farrugia@gov.mt">Godwin.farrugia@gov.mt</a> PSURs may also be sent on CD/DVD. Please do not send paper versions.</i></p>	<p>Medicines Evaluation Board Agency Veterinary Medicinal Products Unit Graadt van Roggenweg 500, 3531 AH Utrecht P.O.Box 8275, 3503 RG Utrecht <b>THE NETHERLANDS</b></p> <p><i>All non-CAP PSURs can be sent via CESP. Otherwise Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:vetpsurs@cbg-meb.nl">vetpsurs@cbg-meb.nl</a> Please do not send paper versions. If you have question or problems contact us via <a href="mailto:vetpharvig@cbg-meb.nl">vetpharvig@cbg-meb.nl</a></i></p>

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<p>The Norwegian Medicines Agency P.O. box 240 Skøyen N-0213 Oslo <b>NORWAY</b></p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:post@noma.no">post@noma.no</a> or via CESP. Please contact the above NCA concerning the required format for electronic files.</i></p>	<p>Office for Registration of Medicinal Products, Medical Devices and Biocides Department of veterinary medicinal products Al. Jerozolimskie 181C 02-222 Warszawa <b>POLAND</b> Fax: +48 22 492 11-09</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:psur_wet@urpl.gov.pl">psur_wet@urpl.gov.pl</a></i></p>
<p>Direção Geral de Alimentação e Veterinária Sistema Nacional de Farmacovigilância Veterinária Campo Grande, n.º 50 1700-093 Lisboa <b>PORTUGAL</b> Fax: + 351 217 808 251</p> <p><i>For electronic submission of non-CAP PSURs, please consult the above NCA or website as follows: <a href="http://www.dgv.min-agricultura.pt">www.dgv.min-agricultura.pt</a></i></p>	<p>Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar 39 Dudului Street Sector 6 060603 Bucharest <b>ROMANIA</b> Fax: +40 21 312 49 67</p> <p><i>All non-CAP PSURs can be sent via CESP. Eudralink<sup>1</sup> submission of PSURs should be sent to: <a href="mailto:icbmv@icbmv.ro">icbmv@icbmv.ro</a> Please do not send paper versions. If you have question or problems contact us via <a href="mailto:icbmv@icbmv.ro">icbmv@icbmv.ro</a></i></p>
<p>Institute for State Control of Veterinary Biologicals and Medicaments Biovetská 34 P.O.Box 52/C 949 01 Nitra <b>SLOVAK REPUBLIC</b> Fax: +421 37 651 79 15</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs should be sent to: <a href="mailto:psur@uskvbl.sk">psur@uskvbl.sk</a> or <a href="mailto:uskvbl@uskvbl.sk">uskvbl@uskvbl.sk</a></i></p>	<p>Departamento de Medicamentos Veterinarios Agencia Española de Medicamentos y Productos Sanitarios C/ Campezo, 1 Parque Empresarial Las Mercedes; Edificio 8 28022 Madrid <b>SPAIN</b> Fax: +34 91 822 54 43</p> <p><i>All non-CAP PSURs should be sent via CESP. Temporarily, PSURs could also be sent to: <a href="mailto:PSURs_veterinaria@aemps.es">PSURs_veterinaria@aemps.es</a>. Paper copies of PSUR are accepted. For more information please see: <a href="http://www.aemps.gob.es/informa/notasInformativas/industria/2014/NI-MVET_11-2014-envio-electronico-documentos.htm">http://www.aemps.gob.es/informa/notasInformativas/industria/2014/NI-MVET_11-2014-envio-electronico-documentos.htm</a></i></p>

<p>Javna agencija Republike Slovenije za zdravila in medicinske pripomočke Sektor za regulativo zdravil za uporabo v veterinarski medicini Slovenčeva ulica 22 1000 Ljubljana <b>SLOVENIA</b> Fax: +386-8-2000-510</p> <p><i>All non-CAP PSURs should be preferably sent via CESP. Otherwise Eudralink<sup>1</sup> submission of PSURs can be sent to: <a href="mailto:v-farmakovigilanca@jazmp.si">v-farmakovigilanca@jazmp.si</a></i></p>	<p>Läkemedelsverket P.O. Box 26 SE-751 03 Uppsala <b>SWEDEN</b> (Delivery address: Dag Hammarskjölds väg 42) Fax: +46 18 548566</p> <p><i>Eudralink<sup>1</sup> submission of non-CAP PSURs is encouraged and should be sent to: <a href="mailto:RIC@mpa.se">RIC@mpa.se</a> or via CESP. If CESP cannot be used and the package is too big for Eudralink, a CD/DVD should be sent to the address above.</i></p>
<p>Veterinary Medicines Directorate Woodham Lane, New Haw Addlestone Surrey KT15 3LS <b>UNITED KINGDOM</b></p> <p><i>All non-CAP PSURs can be sent via CESP. Alternatively Eudralink<sup>1</sup> submission of PSURs should be sent to: <a href="mailto:psur_submissions@vmd.defra.gsi.gov.uk">psur_submissions@vmd.defra.gsi.gov.uk</a></i></p>	