



SOP/V/4023 – Annex I
July 2020
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 AUSTRIA</p> <p><i>All non-CAP PSURs should be sent via CESP. Otherwise Eudralink¹ submission of PSURs should be sent to: basg-v-phv@basg.gv.at</i></p>	<p>Federal Agency for Medicines and Health Products Eurostation bloc II Place Victor Horta 40, bte 40 1060 Bruxelles BELGIUM Fax: +32 2 528 41 36</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: psurv@fagg-afmps.be 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 BULGARIA Fax: +359 2 425 06 35</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: s_branchev@itp.bg</i></p>	<p>Faculty of Veterinary Medicine University of Zagreb Department of Pharmacology and Toxicology Heinzlova 55, 10000 Zagreb CROATIA Fax: + 385 1 2390 159</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: psur@vef.hr</i></p>

¹ 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 CZECH REPUBLIC Fax: +420 541 210 026</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: adr@uskvbl.cz</i></p>	<p>Ministry of Agriculture, Rural Development and Environment Veterinary Services 1417 Nicosia CYPRUS Fax: +357 22 8051 22</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: pharmacovigilance@vs.moa.gov.cy 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 DENMARK T: +45 44 88 95 95</p> <p><i>All non-CAP PSURs should be sent via CESP or Eudralink¹ submission of PSURs to: DK-VET@dkma.dk</i></p>	<p>Ravimiamet State Agency of Medicines Department of Marketing Authorisations Nooruse 1 50411 Tartu ESTONIA Fax: +372 7 37 41 42</p> <p><i>All non-CAP PSURs should be sent via CESP. Otherwise Eudralink¹ submission of PSURs should be sent to: documentation@ravimiamet.ee</i></p>
<p>Amalia Papadaki National Organisation for Medicines Veterinary Section 284 Mesogion Avenue Holargos 15562 Athens GREECE T: +30 213 20 40 213</p> <p><i>All non-CAP PSURs should be sent via CESP or Eudralink¹ submission of PSURs should be sent to: psurvet@eof.gr</i></p>	<p>FIMEA – Finnish Medicines Agency Veterinary Pharmacovigilance P.O. Box 55 FI-00034 FIMEA FINLAND</p> <p><i>Non-CAP PSURs should be submitted via CESP or CD/DVD.</i></p>

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<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 FRANCE Fax: +33 2 9994 6671</p> <p><i>All non-CAP PSURs should be sent via CESP. Otherwise Eudralink¹ submission of non-CAP PSURs should be sent to : secphv@anses.fr</i></p>	<p><u><i>For Immunological Products</i></u> Paul-Ehrlich-Institut Paul-Ehrlich-Straße 51-59 63225 Langen GERMANY Fax: +49 6103 771279</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: vetmittelsicherheit@pei.de</i></p>
<p><u><i>For Pharmaceutical Products</i></u> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit Abteilung 3 Mauerstr. 39-42 10117 Berlin GERMANY Fax: +49 3018 444 89999</p> <p><i>Non-CAP PSURs should be submitted via CESP and alternatively via Eudralink¹ to: PSUR@bvl.bund.de</i></p>	<p>National Food Chain Safety Office Directorate of Veterinary Medicinal Products Szállás Utca 8 1107 Budapest HUNGARY</p> <p><i>Electronic submission of non-CAP PSURs should be sent via CESP or Eudralink¹ to E-Pharmacovigilance@nebih.gov.hu</i></p>
<p>Icelandic Medicines Agency Vínlandsleið 14 IS-113 Reykjavík ICELAND 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 Eudralink¹ or email.</i></p>	<p>Ministry of Health Office 4 – DGSAF Via G. Ribotta, 5 00144 Roma ITALY Fax: +39 06 59 94 69 49</p> <p><i>All PSURs should preferably be sent via CESP. Eudralink¹ submission of non-CAP PSURs may be sent to: farmacovigilanzavet@sanita.it</i></p>

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<p>Receipts and Validation Department Health Products Regulatory Authority Earlsfort Centre; Earlsfort Terrace Dublin 2 IRELAND Fax: +353 1 676 78 36</p> <p><i>Non-CAP PSURs should preferably be submitted via CESP, or alternatively via Eudralink¹ to: submissions@hpra.ie</i></p>	<p>Food and Veterinary Service Peldu street 30 Riga LV-1050 LATVIA</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: vzr@pvd.gov.lv 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 LITHUANIA Fax: +370 37 406820</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: psur@nmvrvl.lt</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 LUXEMBOURG Fax: +352 478 50527</p> <p><i>Please contact the above NCA concerning Eudralink¹ submission of non-CAP PSURs.</i></p>
<p>Veterinary Medicines Section Animal Health and Welfare Department Abattoir Square Alberttown MRS1123 Marsa MALTA Tel: +356 22925355</p> <p><i>Submission of non-CAP PSURs should be sent to veterinarymedicine@gov.mt 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 THE NETHERLANDS</p> <p><i>All non-CAP PSURs can be sent via CESP. Otherwise Eudralink¹ submission of non-CAP PSURs should be sent to: vetpsurs@cbg-meb.nl Please do not send paper versions. If you have question or problems contact us via vetpharvig@cbg-meb.nl</i></p>

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<p>The Norwegian Medicines Agency P.O. box 240 Skøyen N-0213 Oslo NORWAY</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: post@noma.no 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 POLAND Fax: +48 22 492 11 09</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: psur_wet@urpl.gov.pl</i></p>
<p>Direção Geral de Alimentação e Veterinária Sistema Nacional de Farmacovigilância Veterinária Campo Grande, n.º 50 1700-093 Lisboa PORTUGAL Fax: + 351 217 808 251</p> <p><i>All non-CAP PSURs should preferably be sent via CESP. If CESP is not possible for the company, use Eudralink¹ submission of PSURs or normal email to psur-v-submission@dgav.pt</i></p> <p><i>Please only submit via one of the above methods.</i></p> <p><i>If you have any questions or problems, please consult the above NCA or website as follows: www.dgv.min-agricultura.pt</i></p>	<p>Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar 39 Dudului Street Sector 6 060603 Bucharest ROMANIA Fax: +40 21 312 49 67</p> <p><i>All non-CAP PSURs can be sent via CESP. Eudralink¹ submission of PSURs should be sent to: icbmv@icbmv.ro</i></p> <p><i>Please do not send paper versions.</i></p> <p><i>If you have questions or problems, contact us via icbmv@icbmv.ro</i></p>
<p>Institute for State Control of Veterinary Biologicals and Medicaments Biovetská 34 P.O.Box 52/C 949 01 Nitra SLOVAK REPUBLIC Fax: +421 37 651 79 15</p> <p><i>Eudralink¹ submission of non-CAP PSURs should be sent to: psur@uskvbl.sk or uskvbl@uskvbl.sk</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 SPAIN 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: PSURs_veterinaria@aemps.es. Paper copies of PSUR are accepted. For more information please see: http://www.aemps.gob.es/informa/notasInformativas/industria/2014/NI-MVET_11-2014-envio-electronico-documentos.htm</i></p>

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<p>Javna agencija Republike Slovenije za zdravila in medicinske pripomočke Sektor za regulativo zdravil za uporabo v veterinarski medicini Slovenčeva ulica 22 1000 Ljubljana SLOVENIA Fax: +386-8-2000-510</p> <p><i>All non-CAP PSURs should preferably be sent via CESP. Otherwise Eudralink¹ submission of PSURs can be sent to: v-farmakovigilanca@jazmp.si</i></p>	<p>Läkemedelsverket P.O. Box 26 SE-751 03 Uppsala SWEDEN (Delivery address: Dag Hammarskjölds väg 42) Fax: +46 18 548566</p> <p><i>Eudralink¹ submission of non-CAP PSURs is encouraged and should be sent to: RIC@mpa.se or via CESP. If CESP cannot be used and the package is too big for Eudralink¹, a CD/DVD should be sent to the address above.</i></p>
<p>Veterinary Medicines Directorate Woodham Lane, New Haw Addlestone Surrey KT15 3LS UNITED KINGDOM</p> <p><i>All non-CAP PSURs can be sent via CESP. Alternatively, Eudralink¹ submission of PSURs should be sent to: psur.submissions@vmd.gov.uk</i></p>	

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