



SOP/V/4023 – Annex I
January 2018
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

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| <p>Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH Austrian Agency for Health and Food Safety Traisengasse 5 1200 Wien AUSTRIA</p> <p><i>All PSURs should be sent via the Common European Submission Portal (CESP). Otherwise electronic (Eudralink¹) submission of PSURs should be sent to: basg-v-phv@ages.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>Electronic (Eudralink¹) submission of PSURs should be sent to: psurv@fagg-afmps.be PSURs may also be sent via the Common European Submission Portal (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>Electronic (Eudralink¹) submission of PSURs should be sent to: s_branchev@itp.bg</i></p> | <p>Faculty of Veterinary Medicine University of Zagreb Department of Pharmacology and Toxicology HeinzeloVA 55, 10000 Zagreb CROATIA Fax: + 385 1 2390 159</p> <p><i>Electronic (Eudralink¹) submission of 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



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| <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>Electronic (Eudralink¹) submission of 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>Electronic (Eudralink¹) submission of 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 PSURs should be sent via the Common European Submission Portal (CESP) or via electronic (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 PSURs should be sent via the Common European Submission Portal (CESP). Otherwise electronic (Eudralink¹) submission of PSURs should be sent to: documentation@ravimiamet.ee</i></p> |
| <p>Dr Helen Adam-Amenta National Organisation for Medicines Veterinary Section 284 Mesogion Avenue Holargos 15562 Athens GREECE Fax: +30 21 06 53 75 91</p> <p><i>Electronic (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>PSURs should be submitted via CESP or in 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 FRANCE Fax: +33 2 9994 6671</p> | |

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| <p>All PSURs should be sent via the Common European Submission Portal (CESP).</p> <p>Otherwise electronic (Eudralink¹) submission of PSURs should be sent to : secphv@anses.fr</p> | |
| <p><i>For Immunological Products</i> Paul-Ehrlich-Institut Paul-Ehrlich-Straße 51-59 63225 Langen GERMANY Fax: +49 6103 771279</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: vetmittelsicherheit@pei.de</i></p> | <p><i>For Pharmaceutical Products</i> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit Abteilung 3 Mauerstr. 39-42 10117 Berlin GERMANY Fax: +49 3018 444 89999</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: PSUR@bvl.bund.de</i></p> |
| <p>Dr Edit Nagy National Food Chain Safety Office Directorate of Veterinary Medicinal Products Szállás Utca 8 1107 Budapest HUNGARY Fax: +36 1 262 28 39</p> <p><i>Electronic submission of PSURs should be sent by Eudralink to nagye@nebih.gov.hu or via the Common European Submission Portal (CESP).</i></p> | <p>Icelandic Medicines Agency Vinlandsleið 14 IS-113 Reykjavík ICELAND Fax: +354 561 21 70</p> <p><i>PSURs should preferably be submitted via CESP or less preferably on CD/DVD – but not via Eudralink or by e-mail.</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>Electronic (Eudralink¹) submission of PSURs should be sent to: r.quondam@sanita.it farmacovigilanzavet@sanita.it</i></p> | <p>Scientific Officer – Pharmacovigilance Veterinary Sciences Department Health Products Regulatory Authority Earlsfort Centre; Earlsfort Terrace Dublin 2 IRELAND Fax: +353 1 676 78 36</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: vetsafety@hpra.ie</i></p> |
| <p>Food and Veterinary Service Peldu street 30 Riga LV-1050 LATVIA Fax: +371 67322727</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: vzr@pvd.gov.lv or via the Common European Submission Portal (CESP).</i></p> | <p>National Food and Veterinary Risk Assessment Institute Veterinary Medicines and Biocides Assessment Unit J.Naujalio g. 21b 48332 Kaunas 26 LITHUANIA Fax: +370 37 406820</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: psur@nmvrvi.lt</i></p> |

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| <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 electronic (Eudralink¹) submission of PSURs.</i></p> | <p>Mr Kenneth Mifsud Food and Veterinary Division Abattoir Square Albertown CMR 02 Marsa MALTA Fax: +356 21 23 81 05</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: Godwin.farrugia@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 PSURs can be sent via the Common European Submission Portal (CESP). Otherwise electronic (Eudralink¹) submission of 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> | <p>Statens Legemiddelverk P.b. 6167 Etterstad 0602 Oslo NORWAY</p> <p><i>Electronic (Eudralink¹) submission of PSURs should be sent to: post@noma.no or via the Common European Submission Portal (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>Electronic (Eudralink¹) submission of 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>Electronic (Eudralink¹) submission of PSURs for CAPs is encouraged and should be sent to: psur-v-submission@dgav.pt For all other PSURs, please consult the above NCA or website as follows: www.dgv.min-agricultura.pt</i></p> |

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| <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 PSURs can be sent via the Common European Submission portal (CESP), electronic (Eudralink¹) submission of PSURs should be sent to: icbm@icbm.ro Please do not send paper versions. If you have question or problems contact us via icbm@icbm.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>Electronic (Eudralink¹) submission of 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 PSURs should be sent via the Common European Submission Portal (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> | <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 PSURs should be preferably sent via the Common European Submission Portal (CESP). Otherwise electronic (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>Electronic (Eudralink¹) submission of PSURs is encouraged and should be sent to: RIC@mpa.se or through the CESP (see: cesp.hma.eu). 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 UNITED KINGDOM</p> <p><i>All PSURs can be sent via the Common European Submission Portal (CESP) see http://cesp.hma.eu/ Alternatively electronic (Eudralink¹) submission of PSURs should be sent to: psur.submissions@vmd.defra.gsi.gov.uk</i></p> |

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