20 November 2024

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Veterinary Medicines Division

**APPENDIX I**

List of details of the national reporting systems to report adverse events (side effects) for use in section 3.6 “Adverse events” of SPC and section 7 “Adverse events” of package leaflet

No reference to the Appendix I should be included in the printed packaging materials. **Only** the actual details of the national adverse event (pharmacovigilance) reporting system (as listed within this Appendix I) of the concerned Member State(s) shall be displayed on the printed version.

Bracketing convention:

[text]: For guidance only. This text should not be included on the printed packaging materials.

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| **België/Belgique/Belgien**  [Dutch]  [www.eenbijwerkingmelden-dieren.be](http://www.eenbijwerkingmelden-dieren.be/)  of mail: [adversedrugreactions\_vet@fagg-afmps.be](mailto:adversedrugreactions_vet@fagg-afmps.be)  [French]  [www.notifieruneffetindesirable-animaux.be/](https://www.notifieruneffetindesirable-animaux.be/)  ou mail: [adversedrugreactions\_vet@fagg-afmps.be](mailto:adversedrugreactions_vet@fagg-afmps.be)  [German] – N/A | **Lietuva**  Valstybinė maisto ir veterinarijos tarnyba  El. paštas: [vaistu.registracija@vmvt.lt](mailto:vaistu.registracija@vmvt.lt)  Pranešimo forma:  <https://vmvt.lrv.lt/lt/fb/> |
| **България**  Bulgarian Food Safety Agency  Website:  <https://kvmp.bfsa.bg/phv> | **Luxembourg/Luxemburg**  Division de la pharmacie et des médicaments de la Direction de la santé  Mail : [luxvet@ms.etat.lu](mailto:luxvet@ms.etat.lu) |
| **Česká republika**  Ústav pro státní kontrolu veterinárních biopreparátů a léčiv  Hudcova 56a  621 00 Brno  Mail: [adr@uskvbl.cz](mailto:adr@uskvbl.cz)  Webové stránky: <http://www.uskvbl.cz/cs/farmakovigilance> | **Magyarország**  Nemzeti Élelmiszerlánc-biztonsági Hivatal  Állatgyógyászati Termékek Igazgatósága  Postafiók 30  H-1525 Budapest  E-mail: [E-pharmacovigilance@nebih.gov.hu](mailto:E-pharmacovigilance@nebih.gov.hu)  Honlap: <https://portal.nebih.gov.hu/-/pharmacovigilance> |
| **Danmark**  Lægemiddelstyrelsen  Axel Heides Gade 1  DK-2300 København S  Websted: [www.meldenbivirkning.dk](http://www.meldenbivirkning.dk) | **Malta**  Veterinary Regulation Directorate  Albertown,  Marsa MRS 1123, Malta  ADR Reporting Form  [https://agricultureservices.gov.mt](https://agricultureservices.gov.mt/) |

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| **Deutschland**  Bundesamt für Verbraucherschutz  und Lebensmittelsicherheit  Abt. 3 Tierarzneimittel  Pharmakovigilanz  E-Mail: uaw@bvl.bund.de  Internet: https://www.vet-uaw.de  [www.bvl.bund.de](http://www.bvl.bund.de)  [For immunologicals, monoclonal antibodies for immunotherapy, novel therapies for immunotherapy, allergens]  [Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel  Paul-Ehrlich-Institut]  Website: <https://www.vet-uaw.de/> | **Nederland**  Agentschap College ter Beoordeling van Geneesmiddelen - Bureau Diergeneesmiddelen  Bijwerking diergeneesmiddel melden via: [www.diergeneesmiddeleninformatiebank.nl](http://www.diergeneesmiddeleninformatiebank.nl) |
| **Eesti**  [www.ravimiamet.ee](http://www.ravimiamet.ee) | **Norge**  Direktoratet for medisinske produkter:  [www.dmp.no/bivirkningsmelding-vet](http://www.dmp.no/bivirkningsmelding-vet) |
| **Ελλάδα**  Εθνικός Οργανισμός Φαρμάκων  Μεσογείων 284  GR-15562 Χολαργός, Αθήνα  Τηλ: + 30 21 32040213  e-mail: vetpharmacovigilance@eof.gr  Ιστότοπος: <http://www.eof.gr> | **Österreich**  Bundesamt für Sicherheit im Gesundheitswesen  Traisengasse 5, AT-1200 Wien  E-Mail: basg-v-phv@basg.gv.at  Website: <https://www.basg.gv.at/> |
| **España**  Tarjeta verde: <http://bit.ly/tarjeta_verde>  o  NOTIFICAVET: <https://sinaem.aemps.es/fvvet/NotificaVet/> | **Polska**  Urząd Rejestracji Produktów Leczniczych,  Wyrobów Medycznych i Produktów Biobójczych  Al. Jerozolimskie 181C  PL-02-222 Warszawa  Tel.: +48 22 49-21-687  Faks: +48 22 49-21-605  Adres e-mail: [pw@urpl.gov.pl](mailto:pw@urpl.gov.pl)  Strona internetowa: [https://smz.ezdrowie.gov.pl](https://smz.ezdrowie.gov.pl#_blank) |
| **France**  Agence Nationale du Médicament Vétérinaire (ANMV)  Site internet : <https://pharmacovigilance-anmv.anses.fr/> | **Portugal**  Direção Geral de Alimentação e Veterinária (DGAV)  [farmacovigilancia.vet@dgav.pt](mailto:farmacovigilancia.vet@dgav.pt) |
| **Hrvatska**  [www.farmakovigilancija.hr](http://www.farmakovigilancija.hr) | **România**  [farmacovigilenta@ansvsa.ro](mailto:farmacovigilenta@ansvsa.ro)  [icbmv@icbmv.ro](mailto:icbmv@icbmv.ro) |
| **Ireland**  HPRA Pharmacovigilance  Website: [www.hpra.ie](http://www.hpra.ie) | **Slovenija**  Javna agencija Republike Slovenije za zdravila in medicinske pripomočke <https://www.jazmp.si/spletni-obrazec/> |
| **Ísland**  [www.lyfjastofnun.is](http://www.lyfjastofnun.is) | **Slovenská republika**  Ústav štátnej kontroly veterinárnych biopreparátov a liečiv  e-mail: [neziaduce\_ucinky@uskvbl.sk](mailto:neziaduce_ucinky@uskvbl.sk)  Webová stránka: [www.uskvbl.sk](http://www.uskvbl.sk) časť Farmakovigilancia |
| **Italia**  Ministero della Salute (DGSAF)  Ufficio 4 - Medicinali Veterinari  Sito web:  <https://www.salute.gov.it/farmacovigilanzaveterinaria> | **Suomi/Finland**  [Finnish]  Lääkealan turvallisuus- ja kehittämiskeskus Fimea  www-sivusto: <https://www.fimea.fi/elainlaakkeet/>  [Swedish]  Säkerhets- och utvecklingscentret för läkemedelsområdet Fimea  webbplats: <https://www.fimea.fi/web/sv/veterinar> |
| **Κύπρος**  Κτηνιατρικές Υπηρεσίες  1417, Λευκωσία, Κύπρος  <http://www.moa.gov.cy/moa/vs/vs.nsf> | **Sverige**  Läkemedelsverket  Webbplats: [www.lakemedelsverket.se](http://www.lakemedelsverket.se) |
| **Latvija**  <https://www.pvd.gov.lv/lv> | **United Kingdom (Northern Ireland)**  Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>  e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk) |

1. Version 4: All Member States details update (November 2024)

   Version 3: DE and RO details updated (Mar 2023)

   Version 2: HU and ES details updated (Nov 2022) [↑](#footnote-ref-2)