20 November 2024

EMA/217477/2022, version 4[[1]](#footnote-2)

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[French][www.notifieruneffetindesirable-animaux.be/](https://www.notifieruneffetindesirable-animaux.be/)ou mail: adversedrugreactions\_vet@fagg-afmps.be[German] – N/A | **Lietuva**Valstybinė maisto ir veterinarijos tarnybaEl. paštas: vaistu.registracija@vmvt.ltPranešimo forma:<https://vmvt.lrv.lt/lt/fb/> |
| **България**Bulgarian Food Safety AgencyWebsite: <https://kvmp.bfsa.bg/phv> | **Luxembourg/Luxemburg**Division de la pharmacie et des médicaments de la Direction de la santéMail : luxvet@ms.etat.lu |
| **Česká republika**Ústav pro státní kontrolu veterinárních biopreparátů a léčiv Hudcova 56a 621 00 BrnoMail: adr@uskvbl.czWebové stránky: <http://www.uskvbl.cz/cs/farmakovigilance> | **Magyarország**Nemzeti Élelmiszerlánc-biztonsági HivatalÁllatgyógyászati Termékek IgazgatóságaPostafiók 30 H-1525 BudapestE-mail: E-pharmacovigilance@nebih.gov.huHonlap: <https://portal.nebih.gov.hu/-/pharmacovigilance>  |
| **Danmark**LægemiddelstyrelsenAxel Heides Gade 1DK-2300 København SWebsted: [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 Verbraucherschutzund LebensmittelsicherheitAbt. 3 TierarzneimittelPharmakovigilanzE-Mail: uaw@bvl.bund.deInternet: 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 ArzneimittelPaul-Ehrlich-Institut]Website: <https://www.vet-uaw.de/> | **Nederland**Agentschap College ter Beoordeling van Geneesmiddelen - Bureau DiergeneesmiddelenBijwerking 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 ΦαρμάκωνΜεσογείων 284GR-15562 Χολαργός, ΑθήναΤηλ: + 30 21 32040213e-mail: vetpharmacovigilance@eof.grΙστότοπος: <http://www.eof.gr> | **Österreich**Bundesamt für Sicherheit im GesundheitswesenTraisengasse 5, AT-1200 WienE-Mail: basg-v-phv@basg.gv.atWebsite: <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 BiobójczychAl. Jerozolimskie 181CPL-02-222 WarszawaTel.: +48 22 49-21-687Faks: +48 22 49-21-605Adres e-mail: pw@urpl.gov.plStrona 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 |
| **Hrvatska**[www.farmakovigilancija.hr](http://www.farmakovigilancija.hr) | **România** farmacovigilenta@ansvsa.ro icbmv@icbmv.ro  |
| **Ireland**HPRA PharmacovigilanceWebsite: [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 liečive-mail: neziaduce\_ucinky@uskvbl.skWebová stránka: [www.uskvbl.sk](http://www.uskvbl.sk) časť Farmakovigilancia |
| **Italia**Ministero della Salute (DGSAF)Ufficio 4 - Medicinali VeterinariSito web:<https://www.salute.gov.it/farmacovigilanzaveterinaria> | **Suomi/Finland**[Finnish]Lääkealan turvallisuus- ja kehittämiskeskus Fimeawww-sivusto: <https://www.fimea.fi/elainlaakkeet/>[Swedish]Säkerhets- och utvecklingscentret för läkemedelsområdet Fimeawebbplats: <https://www.fimea.fi/web/sv/veterinar> |
| **Κύπρος**Κτηνιατρικές Υπηρεσίες1417, Λευκωσία, Κύπρος<http://www.moa.gov.cy/moa/vs/vs.nsf> | **Sverige**LäkemedelsverketWebbplats: [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 |

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)