



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2024
EMA/217477/2022, version 4¹
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.

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)



België/Belgique/Belgien

[Dutch]

www.eenbijwerkingmelden-dieren.beof mail: adversedrugreactions_vet@fagg-afmps.be

[French]

www.notifieruneffetindesirable-animaux.be/ou mail: adversedrugreactions_vet@fagg-afmps.be

[German] – N/A

България

Bulgarian Food Safety Agency

Website:

<https://kvmp.bfsa.bg/phv>**Česká republika**Ústav pro státní kontrolu veterinárních
biopreparátů a léčiv

Hudcova 56a

621 00 Brno

Mail: adr@uskvbl.cz

Webové stránky:

<http://www.uskvbl.cz/cs/farmakovigilance>**Danmark**

Lægemiddelstyrelsen

Axel Heides Gade 1

DK-2300 København S

Websted: www.meldenbivirkning.dk**Lietuva**

Valstybinė maisto ir veterinarijos tarnyba

El. paštas: vaistu.registracija@vmvt.lt

Pranešimo forma:

<https://vmvt.lrv.lt/lt/fb/>**Luxembourg/Luxemburg**

Division de la pharmacie et des médicaments de la

Direction de la santé

Mail : luxvet@ms.etat.lu**Magyarország**

Nemzeti Élelmiszerlánc-biztonsági Hivatal

Állatgyógyászati Termékek Igazgatósága

Postafiók 30

H-1525 Budapest

E-mail: E-pharmacovigilance@nebih.gov.huHonlap: <https://portal.nebih.gov.hu/-/pharmacovigilance>**Malta**

Veterinary Regulation Directorate

Alberttown,

Marsa MRS 1123, Malta

ADR Reporting Form

<https://agricultureservices.gov.mt>

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

[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/>

Eesti

www.ravimiamet.ee

Ελλάδα

Εθνικός Οργανισμός Φαρμάκων
Μεσογείων 284
GR-15562 Χολαργός, Αθήνα
Τηλ: + 30 21 32040213
e-mail: vetpharmacovigilance@eof.gr
Ιστότοπος: <http://www.eof.gr>

España

Tarjeta verde: http://bit.ly/tarjeta_verde
o
NOTIFICAVET:
<https://sinaem.aemps.es/fvvet/NotificaVet/>

France

Agence Nationale du Médicament Vétérinaire
(ANMV)
Site internet : <https://pharmacovigilance-anmv.anses.fr/>

Nederland

Agentschap College ter Beoordeling van
Geneesmiddelen - Bureau Diergeneesmiddelen
Bijwerking diergeneesmiddel melden via:
www.diergeneesmiddeleninformatiebank.nl

Norge

Direktoratet for medisinske produkter:
www.dmp.no/bivirkningsmelding-vet

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/>

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
Strona internetowa: <https://smz.ezdrowie.gov.pl>

Portugal

Direção Geral de Alimentação e Veterinária
(DGAV)
farmacovigilancia.vet@dgav.pt

Hrvatska

www.farmakovigilancija.hr

România

farmacovigilenta@ansvsa.ro

icbmrv@icbmrv.ro

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Ísland

www.lyfjastofnun.is

Italia

Ministero della Salute (DGSAF)

Ufficio 4 - Medicinali Veterinari

Sito web:

<https://www.salute.gov.it/farmacovigilanzaveterinaria>

Κύπρος

Κτηνιατρικές Υπηρεσίες

1417, Λευκωσία, Κύπρος

<http://www.moa.gov.cy/moa/vs/vs.nsf>

Latvija

<https://www.pvd.gov.lv/lv>

Slovenija

Javna agencija Republike Slovenije za zdravila in medicinske pripomočke

<https://www.jazmp.si/spletni-obrazec/>

Slovenská republika

Ústav štátnej kontroly veterinárnych biopreparátov a liečiv

e-mail: neziaduce_ucinky@uskvbl.sk

Webová stránka: www.uskvbl.sk časť

Farmakovigilancia

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>

Sverige

Läkemedelsverket

Webbplats: www.lakemedelsverket.se

United Kingdom (Northern Ireland)

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk