EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2026
EMA/67830/2013, Version 35[1]
Human Medicines Division

APPENDIX V

List of details of the national reporting systems to communicate adverse reactions (side effects) for use in section 4.8 "Undesirable effects" of SmPC and section 4 "Possible side effects" of package leaflet.

No reference to the Appendix V should be included in the printed packaging materials. **Only** the actual details of the national reporting system (as listed within this Appendix V) 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] Changes implemented in the different revisions:
V.33: HU details updated (3 October 2025)
V.34: LT details updated (16 December 2025)
V.35: PL and CZ details updated (20 March 2026)

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI, also referred to as the Windsor Framework.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

België/Belgique/Belgien
[Dutch]
Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
www.fagg.be
Afdeling Vigilantie:
Website: www.eenbijwerkingmelden.be
e-mail: adr@fagg-afmps.be

[French]
Agence fédérale des médicaments et des produits de santé
www.afmps.be
Division Vigilance:
Site internet: www.notifieruneffetindesirable.be
e-mail: adr@fagg-afmps.be

[German]
Föderalagentur für Arzneimittel und Gesundheitsprodukte
www.afmps.be
Abteilung Vigilanz:
Website: www.notifieruneffetindesirable.be
e-mail: adr@fagg-afmps.be

Lietuva
Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos
Tel.: +370 800 73 568
Informacija pranešimo formos pildymui ir pateikimui: https://vvkt.lrv.lt/lt/

България
Изпълнителна агенция по лекарствата
ул. „Дамян Груев“ № 8
1303 София
Тел.: +359 2 8903417
уебсайт: www.bda.bg

Luxembourg/Luxemburg
[French]
Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé
Site internet : www.guichet.lu/pharmacovigilance

[German]
Centre Régional de Pharmacovigilance de Nancy oder Abteilung Pharmazie und Medikamente (Division de la pharmacie et des médicaments) der Gesundheitsbehörde in Luxemburg
Website : www.guichet.lu/pharmakovigilanz

Česko
webového formuláře
sukl.gov.cz/nezadouciucinky

případně na adresu:
Státní ústav pro kontrolu léčiv
Šrobárova 49/48
100 00 Praha 10
email: farmakovigilance@sukl.gov.cz

Magyarország
Nemzeti Népegészségügyi és Gyógyszerészeti Központ
Postafiók 450
H-1372 Budapest
Honlap: www.nngyk.gov.hu
elektronikus úton történő mellékhatás-bejelentés:
https://mellekhatas.nngyk.gov.hu
e-mail: adr.box@nngyk.gov.hu

Danmark
Lægemiddelstyrelsen
Axel Heides Gade 1
DK-2300 København S
Websted: www.meldenbivirkning.dk

Malta
ADR Reporting Website:
https://medicinesauthority.gov.mt/adrportal

Deutschland
Bundesinstitut für Arzneimittel und Medizinprodukte
Abt. Pharmakovigilanz
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: http://www.bfarm.de

[For vaccines/biological medicinal products]
Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Paul-Ehrlich-Institut
Paul-Ehrlich-Str. 51-59
63225 Langen
Tel: +49 6103 77 0
Fax: +49 6103 77 1234
Website: www.pei.de

Eesti
Ravimiamet
Koduleht: www.ravimiamet.ee

Ελλάδα
Εθνικός Οργανισμός Φαρμάκων
Μεσογείων 284
GR-15562 Χολαργός, Αθήνα
Τηλ: + 30 21 32040337
Ιστότοπος: http://www.eof.gr
http://www.kitrinikarta.gr

España
Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano:
www.notificaRAM.es

France
Agence nationale de sécurité du médicament et des produits de santé (ANSM)
et réseau des Centres Régionaux de Pharmacovigilance
Site internet: https://signalement.social-sante.gouv.fr/

Nederland
Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl

Norge
Direktoratet for medisinske produkter
[For SmPC]
Nettside: www.dmp.no/meldeskjema

[For package leaflet]
Nettside: www.dmp.no/pasientmelding

Österreich
Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 WIEN
ÖSTERREICH
Fax: + 43 (0) 50 555 36207
Website: http://www.basg.gv.at/

Polska
Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych
Al. Jerozolimskie 181C
02-222 Warszawa
Tel.: + 48 22 49 21 301
Faks: + 48 22 49 21 309
Strona internetowa: https://smz.ezdrowie.gov.pl

Portugal
Sítio da internet:
http://www.infarmed.pt/web/infarmed/submissaoram
(preferencialmente)
ou através dos seguintes contactos:
Direção de Gestão do Risco de Medicamentos
Parque da Saúde de Lisboa, Av. Brasil 53
1749-004 Lisboa

Tel: +351 21 798 73 73
Linha do Medicamento: 800222444 (gratuita)
e-mail: farmacovigilancia@infarmed.pt

Hrvatska
Agencija za lijekove i medicinske proizvode (HALMED)
Internetska stranica: www.halmed.hr

România
Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale din România
Str. Aviator Sănătescu nr. 48, sector 1
Bucureşti 011478- RO
e-mail: adr@anm.ro
Website: www.anm.ro

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Slovenija
Javna agencija Republike Slovenije za zdravila in medicinske pripomočke
Sektor za farmakovigilanco
Nacionalni center za farmakovigilanco
Slovenčeva ulica 22
SI-1000 Ljubljana
Tel: +386 (0)8 2000 500
Faks: +386 (0)8 2000 510
e-pošta: h-farmakovigilanca@jazmp.si
spletna stran: www.jazmp.si

Ísland
til Lyfjastofnunar, www.lyfjastofnun.is

Slovenská republika
Štátny ústav pre kontrolu liečiv
Sekcia vigilancie
Kvetná 11
SK-825 08 Bratislava
Tel: + 421 2 507 01 206
e-mail: neziaduce.ucinky@sukl.sk
Tlačivo na hlásenie podozrenia na nežiaduci účinok lieku je na webovej stránke www.sukl.sk v časti Bezpečnosť liekov/Hlásenie podozrení na nežiaduce účinky liekov
Formulár na elektronické podávanie hlásení:
https://portal.sukl.sk/eskadra/

Italia
Agenzia Italiana del Farmaco
Sito web:
https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse

Suomi/Finland
[Finnish]
www-sivusto: www.fimea.fi
Lääkealan turvallisuus- ja kehittämiskeskus Fimea
Lääkkeiden haittavaikutusrekisteri
PL 55
00034 FIMEA

[Swedish]
webbplats: www.fimea.fi
Säkerhets- och utvecklingscentret för läkemedelsområdet Fimea
Biverkningsregistret
PB 55
00034 FIMEA

Κύπρος
Φαρμακευτικές Υπηρεσίες
Υπουργείο Υγείας
CY-1475 Λευκωσία
Τηλ: +357 22608607
Φαξ: + 357 22608669
Ιστότοπος: www.moh.gov.cy/phs

Latvija
Zāļu valsts aģentūra
Jersikas iela 15
Rīga, LV 1003
Tīmekļa vietne: www.zva.gov.lv

Sverige
Läkemedelsverket
Box 26
751 03 Uppsala
Webbplats: www.lakemedelsverket.se

United Kingdom (Northern Ireland)*
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

[for COVID-19 products/treatments]
Yellow Card Scheme
Website: https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store

* Not applicable to centrally authorised medicinal products