29 February 2024

EMA/67830/2013, Version 29[[1]](#footnote-2)

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.

|  |  |
| --- | --- |
| **België/Belgique/Belgien**[Dutch]Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten[www.fagg.be](http://www.fagg.be/)Afdeling Vigilantie:Website: [www.eenbijwerkingmelden.be](http://www.eenbijwerkingmelden.be)e-mail: adr@fagg-afmps.be[French]Agence fédérale des médicaments et des produits de santéwww.afmps.beDivision Vigilance:Site internet: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)e-mail: adr@fagg-afmps.be[German]Föderalagentur für Arzneimittel und Gesundheitsproduktewww.afmps.be Abteilung Vigilanz: Website: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)e-mail: adr@fagg-afmps.be  | **Lietuva**Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijosTel.: 8 800 73568El. paštas: NepageidaujamaR@vvkt.lt[For SmPC]Pranešimo forma pildymui internetu: <https://vapris.vvkt.lt/vvkt-web/public/nrvSpecialist>Pranešimo forma skelbiama <https://www.vvkt.lt/index.php?1399030386>[For package leaflet]Pranešimo forma pildymui internetu: <https://vapris.vvkt.lt/vvkt-web/public/nrv>Pranešimo forma skelbiama <https://www.vvkt.lt/index.php?4004286486> |
| **България**Изпълнителна агенция по лекарстватаул. „Дамян Груев“ № 8 1303 София Teл.: +359 2 8903417уебсайт: [www.bda.bg](http://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](http://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 LuxemburgWebsite : [www.guichet.lu/pharmakovigilanz](http://www.guichet.lu/pharmakovigilanz) |
| **Česká republika**Státní ústav pro kontrolu léčivŠrobárova 48100 41 Praha 10Webové stránky: [www.sukl.cz/nahlasit-nezadouci-ucinek](http://www.sukl.cz/nahlasit-nezadouci-ucinek) | **Magyarország**Nemzeti Népegészségügyi ésGyógyszerészeti KözpontPostafiók 450H-1372 BudapestHonlap: [www.ogyei.gov.hu](http://www.ogyi.hu/)elektronikus bejelentő form: <https://mellekhatas.ogyei.gov.hu/>e-mail: adr.box@ogyei.gov.hu |
| **Danmark**LægemiddelstyrelsenAxel Heides Gade 1DK-2300 København SWebsted: [www.meldenbivirkning.dk](http://www.meldenbivirkning.dk) | **Malta**ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal) |
| **Deutschland**Bundesinstitut für Arzneimittel und MedizinprodukteAbt. PharmakovigilanzKurt-Georg-Kiesinger-Allee 3D-53175 BonnWebsite: <http://www.bfarm.de>[For vaccines/biological medicinal products]Bundesinstitut für Impfstoffe und biomedizinische ArzneimittelPaul-Ehrlich-InstitutPaul-Ehrlich-Str. 51-5963225 LangenTel: +49 6103 77 0Fax: +49 6103 77 1234Website: [www.pei.de](http://www.pei.de) | **Nederland**Nederlands Bijwerkingen Centrum LarebWebsite: [www.lareb.nl](http://www.lareb.nl) |
| **Eesti**RavimiametKoduleht: www.ravimiamet.ee | **Norge**Direktoratet for medisinske produkter[For SmPC]Nettside: [www.dmp.no/meldeskjema](http://www.dmp.no/meldeskjema)[For package leaflet] Nettside: [www.dmp.no/pasientmelding](http://www.dmp.no/pasientmelding) |
| **Ελλάδα**Εθνικός Οργανισμός ΦαρμάκωνΜεσογείων 284GR-15562 Χολαργός, ΑθήναΤηλ: + 30 21 32040337Ιστότοπος: <http://www.eof.gr> <http://www.kitrinikarta.gr> | **Österreich**Bundesamt für Sicherheit im GesundheitswesenTraisengasse 51200 WIENÖSTERREICHFax: + 43 (0) 50 555 36207Website: <http://www.basg.gv.at/> |
| **España**Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano: [www.notificaRAM.es](http://www.notificaRAM.es) | **Polska**Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów BiobójczychAl. Jerozolimskie 181C PL-02 222 WarszawaTel.: + 48 22 49 21 301Faks: + 48 22 49 21 309Strona internetowa: [https://smz.ezdrowie.gov.pl](https://smz.ezdrowie.gov.pl/) |
| **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/> | **Portugal**Sítio da internet: <http://www.infarmed.pt/web/infarmed/submissaoram> (preferencialmente) ou através dos seguintes contactos:Direção de Gestão do Risco de MedicamentosParque da Saúde de Lisboa, Av. Brasil 531749-004 LisboaTel: +351 21 798 73 73Linha do Medicamento: 800222444 (gratuita)e-mail: farmacovigilancia@infarmed.pt |
| **Hrvatska**Agencija za lijekove i medicinske proizvode (HALMED)Internetska stranica: [www.halmed.hr](http://www.halmed.hr) ili potražite HALMED aplikaciju putem Google Play ili Apple App Store trgovine | **România**Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale din RomâniaStr. Aviator Sănătescu nr. 48, sector 1Bucureşti 011478- RO e-mail: adr@anm.roWebsite: [www.anm.ro](http://www.anm.ro) |
| **Ireland**HPRA PharmacovigilanceWebsite: [www.hpra.ie](http://www.hpra.ie)  | **Slovenija**Javna agencija Republike Slovenije za zdravila in medicinske pripomočkeSektor za farmakovigilancoNacionalni center za farmakovigilancoSlovenčeva ulica 22SI-1000 LjubljanaTel: +386 (0)8 2000 500Faks: +386 (0)8 2000 510e-pošta: h-farmakovigilanca@jazmp.sispletna stran: [www.jazmp.si](http://www.jazmp.si/) |
| **Ísland**til Lyfjastofnunar, [www.lyfjastofnun.is](http://www.lyfjastofnun.is) | **Slovenská republika**Štátny ústav pre kontrolu liečivSekcia klinického skúšania liekov a farmakovigilancieKvetná 11SK-825 08 BratislavaTel: + 421 2 507 01 206e-mail: neziaduce.ucinky@sukl.skTlačivo na hlásenie podozrenia na nežiaduci účinok lieku je na webovej stránke [www.sukl.sk](http://www.sukl.sk/) v časti Bezpečnosť liekov/Hlásenie podozrení na nežiaduce účinky liekovFormulár na elektronické podávanie hlásení: <https://portal.sukl.sk/eskadra/>  |
| **Italia**Agenzia Italiana del FarmacoSito web: <https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse> | **Suomi/Finland**[Finnish]www-sivusto: [www.fimea.fi](http://www.fimea.fi)Lääkealan turvallisuus- ja kehittämiskeskus FimeaLääkkeiden haittavaikutusrekisteriPL 5500034 FIMEA[Swedish]webbplats: [www.fimea.fi](http://www.fimea.fi)Säkerhets- och utvecklingscentret för läkemedelsområdet FimeaBiverkningsregistretPB 5500034 FIMEA |
| **Κύπρος**Φαρμακευτικές ΥπηρεσίεςΥπουργείο ΥγείαςCY-1475 ΛευκωσίαΤηλ: +357 22608607Φαξ: + 357 22608669Ιστότοπος: [www.moh.gov.cy/phs](http://www.moh.gov.cy/phs) | **Sverige**LäkemedelsverketBox 26751 03 UppsalaWebbplats: [www.lakemedelsverket.se](http://www.lakemedelsverket.se) |
| **Latvija**Zāļu valsts aģentūraJersikas iela 15Rīga, LV 1003 Tīmekļa vietne: [www.zva.gov.lv](http://www.zva.gov.lv) | **United Kingdom (Northern Ireland)\***Yellow Card SchemeWebsite: [www.mhra.gov.uk/yellowcard](http://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 SchemeWebsite: <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

1. Changes implemented in the different revisions:

**V.26:** FR and SK details updated (15 May 2023)

**V.27:** HU details updated (18 August 2023)

**V.28:** LX and EL details updated (17 January 2024)

**V.29:** Footnotes to reflect the Windsor Framework, and BE and NO details updated (29 February 2024)

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. [↑](#footnote-ref-2)