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.

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| --- | --- |
| **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](mailto:adr@fagg-afmps.be)  [French]  Agence fédérale des médicaments et des produits de santé  www.afmps.be  Division Vigilance:  Site internet: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)  e-mail: [adr@fagg-afmps.be](mailto:adr@fagg-afmps.be)  [German]  Föderalagentur für Arzneimittel und Gesundheitsprodukte  www.afmps.be  Abteilung Vigilanz:  Website: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)  e-mail: [adr@fagg-afmps.be](mailto:adr@fagg-afmps.be) | **Lietuva**  Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos  Tel.: 8 800 73568  El. paštas: [NepageidaujamaR@vvkt.lt](mailto: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 лекарствата  ул. „Дамян Груев“ № 8  1303 София  Teл.: +359 2 8903417  уебсайт: [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 Luxemburg  Website : [www.guichet.lu/pharmakovigilanz](http://www.guichet.lu/pharmakovigilanz) |
| **Česká republika**  Státní ústav pro kontrolu léčiv  Šrobárova 48  100 41 Praha 10  Webové stránky: [www.sukl.cz/nahlasit-nezadouci-ucinek](http://www.sukl.cz/nahlasit-nezadouci-ucinek) | **Magyarország**  Nemzeti Népegészségügyi és  Gyógyszerészeti Központ  Postafiók 450  H-1372 Budapest  Honlap: [www.ogyei.gov.hu](http://www.ogyi.hu/)  elektronikus bejelentő form: <https://mellekhatas.ogyei.gov.hu/>  e-mail: [adr.box@ogyei.gov.hu](mailto:adr.box@ogyei.gov.hu) |
| **Danmark**  Lægemiddelstyrelsen  Axel Heides Gade 1  DK-2300 København S  Websted: [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 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](http://www.pei.de) | **Nederland**  Nederlands Bijwerkingen Centrum Lareb  Website: [www.lareb.nl](http://www.lareb.nl) |
| **Eesti**  Ravimiamet  Koduleht: 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 Φαρμάκων  Μεσογείων 284  GR-15562 Χολαργός, Αθήνα  Τηλ: + 30 21 32040337  Ιστότοπος: <http://www.eof.gr>  <http://www.kitrinikarta.gr> | **Österreich**  Bundesamt für Sicherheit im Gesundheitswesen  Traisengasse 5  1200 WIEN  ÖSTERREICH  Fax: + 43 (0) 50 555 36207  Website: <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 Biobójczych  Al. Jerozolimskie 181C  PL-02 222 Warszawa  Tel.: + 48 22 49 21 301  Faks: + 48 22 49 21 309  Strona 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 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](mailto: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 România  Str. Aviator Sănătescu nr. 48, sector 1  Bucureşti 011478- RO  e-mail: [adr@anm.ro](mailto:adr@anm.ro)  Website: [www.anm.ro](http://www.anm.ro) |
| **Ireland**  HPRA Pharmacovigilance  Website: [www.hpra.ie](http://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](javascript:linkTo_UnCryptMailto('ocknvq,j\/hctocmqxkikncpecBlcbor0uk');) spletna stran: [www.jazmp.si](http://www.jazmp.si/) |
| **Ísland**  til Lyfjastofnunar, [www.lyfjastofnun.is](http://www.lyfjastofnun.is) | | **Slovenská republika**  Štátny ústav pre kontrolu liečiv Sekcia klinického skúšania liekov a farmakovigilancie Kvetná 11 SK-825 08 Bratislava  Tel: + 421 2 507 01 206  e-mail: [neziaduce.ucinky@sukl.sk](mailto:neziaduce.ucinky@sukl.sk)  Tlačivo 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 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](http://www.fimea.fi)  Lääkealan turvallisuus- ja kehittämiskeskus Fimea  Lääkkeiden haittavaikutusrekisteri  PL 55  00034 FIMEA  [Swedish]  webbplats: [www.fimea.fi](http://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](http://www.moh.gov.cy/phs) | | **Sverige**  Läkemedelsverket  Box 26  751 03 Uppsala  Webbplats: [www.lakemedelsverket.se](http://www.lakemedelsverket.se) |
| **Latvija**  Zāļu valsts aģentūra  Jersikas iela 15  Rīga, LV 1003  Tīmekļa vietne: [www.zva.gov.lv](http://www.zva.gov.lv) | | **United Kingdom (Northern Ireland)\***  Yellow Card Scheme  Website: [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 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

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)