19 March 2021

EMA/67830/2013, Version 22[[1]](#footnote-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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **België/Belgique/Belgien**[Dutch]Federaal Agentschap voor Geneesmiddelen en GezondheidsproductenAfdeling Vigilantie

|  |  |
| --- | --- |
| Galileelaan 5/031210 BRUSSEL | Postbus 971000 BRUSSEL Madou |

Website: [www.eenbijwerkingmelden.be](http://www.eenbijwerkingmelden.be)e-mail: adr@fagg.be[French]Agence fédérale des médicaments et des produits de santéDivision Vigilance

|  |  |
| --- | --- |
|  Avenue Galilée 5/031210 BRUSSEL | Boîte Postale 971000 BRUXELLES Madou |

Site internet: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)e-mail: adr@afmps.be[German]Föderalagentur für Arzneimittel und Gesundheitsprodukte Abteilung Vigilanz

|  |  |
| --- | --- |
| Avenue Galilée - Galileelaan 5/03 1210 BRÜSSEL | Postfach 971000 BRÜSSEL Madou |

Website: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)e-mail: adr@fagg-afmps.be  | **Lietuva**VVKT prie LR SAMŽirmūnų g. 139ALT 09120, Vilnius Tel: 8 800 73568Faksas: 8 800 20131El. paštas: NepageidaujamaR@vvkt.ltInterneto svetainė: [www.vvkt.lt](http://www.vvkt.lt) |
| **България**Изпълнителна агенция по лекарстватаул. „Дамян Груев“ № 8 1303 София Teл.: +359 2 8903417уебсайт: [www.bda.bg](http://www.bda.bg/) | **Luxembourg/Luxemburg**Centre Régional de Pharmacovigilance de NancyBâtiment de Biologie Moléculaire et de Biopathologie (BBB)CHRU de Nancy – Hôpitaux de BraboisRue du Morvan54 511 VANDOEUVRE LES NANCY CEDEX Tél: (+33) 3 83 65 60 85 / 87e-mail: crpv@chru-nancy.fr[ou]Direction de la SantéDivision de la Pharmacie et des Médicaments 20, rue de BitbourgL-1273 Luxembourg-HammTél.: (+352) 2478 5592e-mail: pharmacovigilance@ms.etat.luLink pour le formulaire : <https://guichet.public.lu/fr/entreprises/sectoriel/sante/medecins/notification-effets-indesirables-medicaments.html> |
| **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**Országos Gyógyszerészeti és Élelmezés‑egészségügyi IntézetPostafiók 450H-1372 BudapestHonlap: [www.ogyei.gov.hu](http://www.ogyi.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**Statens legemiddelverk[For SmPC]Nettside: [www.legemiddelverket.no/meldeskjema](http://www.legemiddelverket.no/meldeskjema)[For package leaflet] Nettside: [www.legemiddelverket.no/pasientmelding](http://www.legemiddelverket.no/pasientmelding) |
| **Ελλάδα**Εθνικός Οργανισμός ΦαρμάκωνΜεσογείων 284GR-15562 Χολαργός, ΑθήναΤηλ: + 30 21 32040380/337Φαξ: + 30 21 06549585 Ιστότοπος: <http://www.eof.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: [www.signalement-sante.gouv.fr](http://www.signalement-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 Tel: + 4 0757 117 259Fax: +4 0213 163 497e-mail: adr@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 ul. 11SK-825 08 Bratislava 26Tel: + 421 2 507 01 206e-mail: neziaduce.ucinky@sukl.skTlačivo na hlásenie nežiaduceho účinku je na webovej stránke [www.sukl.sk](http://www.sukl.sk/) v časti Bezpečnosť liekov/Hlásenie o nežiaducich účinkochFormulár 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 |

1. Changes implemented in the different revisions:

**V.19:** RO and SK details updated (3 March 2020)

**V.20:** LU, PL and SK details updated (8 October 2020)

**V.21**: BE and CY details and UK (Northern Ireland) heading updated (1 January 2021)

**V.22**: BE details updated (19 March 2021)

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. [↑](#footnote-ref-1)