21 September 2022
EMA/67830/2013, Version 25[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.23: UK, BE and RO details updated (11 January 2022)
V.24: LT details updated (20 January 2022)
V.25: LX details updated (21 September 2022)

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.

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Division Vigilance

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уебсайт: www.bda.bg

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Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
Webové stránky: www.sukl.cz/nahlasit-nezadouci-ucinek

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

Lietuva
Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos
Tel.: 8 800 73568
El. 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

Luxembourg/Luxemburg
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

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Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
Postafiók 450
H-1372 Budapest
Honlap: www.ogyei.gov.hu

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

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

[For vaccines/biological medicinal products]
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Paul-Ehrlich-Str. 51-59
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Eesti
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Ιστότοπος: http://www.eof.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: www.signalement-sante.gouv.fr

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

Norge
Statens legemiddelverk
[For SmPC]
Nettside: www.legemiddelverket.no/meldeskjema

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

Österreich
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Website: http://www.basg.gv.at/

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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 ili potražite HALMED aplikaciju putem Google Play ili Apple App Store trgovine

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Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Slovenija
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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]
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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