IV

*(Fógraí)*

# FÓGRAÍ Ó INSTITIÚIDÍ, Ó CHOMHLACHTAÍ, Ó OIFIGÍ, AGUS Ó GHNÍOMHAIREACHTAÍ AN AONTAIS EORPAIGH

# AN COIMISIÚN EORPACH

## Achoimre ar chinntí an Aontais Eorpaigh maidir le húdaruithe margaíochta i ndáil le táirgí íocshláinte ó 1 Nollaig 2022 go dtí 31 Nollaig 2022

*(Arna fhoilsiú de bhun Airteagal 13 nó Airteagal 38 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle [1]) nó Airteagal 5 de Rialachán (AE) 2019/6 ó Pharlaimint na hEorpa agus ón gComhairle [2]))*

(2023/C 37/01)

[1] IO L 136, 30.4.04, lch. 1.
[2] IO L 4, 7.1.2019, lch. 43.

— **Údarú margaíochta a eisiúint** (Airteagal 13 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

| Dáta an chinnidh | Ainm an táirge íocshláinte | ANI (an tAinm Neamhdhíl-seánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 2.12.2022 | Mycapssa | ochtréitíd | Amryt Pharmaceuticals DAC<br>45 Mespil Road, Dublin 4, Ireland | EU/1/22/1690 | Capsúl gastrai-fhrithsheasmhach, crua | H01CB02 | 5.12.2022 |
| 5.12.2022 | Qdenga | vacsaín deinge cheathair-fhiúsach (beo, caolaithe) | Takeda GmbH<br>Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland | EU/1/22/1699 | Púdar agus tuaslagóir do thuaslagán le haghaidh insteallta | J07BX04 | 6.12.2022 |
| 9.12.2022 | Livmarli | clóiríd maralixibat | Mirum Pharmaceuticals International B.V.<br>Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland | EU/1/22/1704 | Oral solution | A05AX04 | 12.12.2022 |
| 9.12.2022 | Locametz | gozetotide | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/22/1692 | Púdar do thuaslagán le haghaidh insteallta | V09IX14 | 12.12.2022 |
| 9.12.2022 | Pemetrexed Baxter | pemetrexed | Baxter Holding B.V.<br>Kobaltweg 49, 3542 CE Utrecht, Nederland | EU/1/22/1705 | Púdar do thiúchán do thuaslagán le haghaidh insilte | L01BA04 | 13.12.2022 |
| 9.12.2022 | Pluvicto | lutetium ($^{177}$Lu) vipivotide tetraxetan | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/22/1703 | Solution for injection or infusion | V10XX05 | 12.12.2022 |
| 9.12.2022 | Spevigo | spesolimab | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/22/1688 | Tiúchán do thuaslagán le haghaidh insilte | L04AC22 | 12.12.2022 |
| 12.12.2022 | Dimethyl Fumarate Teva | n/a | Teva GmbH<br>Graf-Arco-Straße 3, 89079 Ulm, Deutschland | EU/1/22/1702 | Capsúl gastrai-fhrithsheasmhach, crua | L04AX07 | 3.1.2023 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | ANI (an tAinm Neamhdhíl-seánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 12.12.2022 | Eladynos | abaloparatide | Radius Health (Ireland) Ltd.<br>13 Classon House, Dundrum Business Park, Dundrum, Dublin D14 W9Y3, Ireland | EU/1/22/1706 | Tuaslagán le haghaidh insteallta | H05AA04 | 13.12.2022 |
| 16.12.2022 | Ebvallo | tabelecleucel | Atara Biotherapeutics Ireland Limited<br>Arthur Cox Building, 10 Earlsfort Terrace, Dublin 2 D02 T380, Ireland | EU/1/22/1700 | dispersion for injection | Pending | 16.12.2022 |
| 16.12.2022 | Plerixafor Accord | plerixafor | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/22/1701 | Tuaslagán le haghaidh insteallta | L03AX16 | 19.12.2022 |
| 20.12.2022 | Zynlonta | loncastuximab tesirine | ADC Therapeutics (NL) B.V.<br>Laarderhoogtweg 25, Amsterdam, Noord-Holland, 1101 EB, Nederland | EU/1/22/1695 | Púdar do thiúchán do thuaslagán le haghaidh insilte | L01FX22 | 22.12.2022 |

— **Údarú margaíochta a mhodhnú** (Airteagal 13 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 2.12.2022 | Comirnaty | BioNTech Manufacturing GmbH<br>An der Goldgrube 12, 55131 Mainz, Deutschland | EU/1/20/1528 | 2.12.2022 |
| 2.12.2022 | DuoPlavin | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/10/619 | 5.12.2022 |
| 2.12.2022 | Kaftrio | Vertex Pharmaceuticals (Ireland) Limited<br>Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland | EU/1/20/1468 | 5.12.2022 |
| 2.12.2022 | Kalydeco | Vertex Pharmaceuticals (Ireland) Limited<br>Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland | EU/1/12/782 | 5.12.2022 |
| 2.12.2022 | QINLOCK | Deciphera Pharmaceuticals (Netherlands) B.V.<br>Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland | EU/1/21/1569 | 8.12.2022 |
| 2.12.2022 | Sifrol | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/97/050 | 7.12.2022 |
| 2.12.2022 | Spikevax | MODERNA BIOTECH SPAIN, S.L.<br>Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España | EU/1/20/1507 | 7.12.2022 |
| 2.12.2022 | Trizivir | ViiV Healthcare BV<br>Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland | EU/1/00/156 | 5.12.2022 |
| 2.12.2022 | Trogarzo | Theratechnologies Europe Limited<br>4th Floor, 2 Hume Street, Dublin 2, D02 DV24, Ireland | EU/1/19/1359 | 14.12.2022 |
| 2.12.2022 | Trydonis | Chiesi Farmaceutici S.p.A.<br>Via Palermo 26/A, 43122 Parma, Italia | EU/1/18/1274 | 5.12.2022 |
| 2.12.2022 | Zyclara | Viatris Healthcare Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/12/783 | 6.12.2022 |
| 5.12.2022 | Shingrix | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, 1330 Rixensart, Belgique | EU/1/18/1272 | 6.12.2022 |
| 5.12.2022 | Steglujan | Merck Sharp & Dohme B.V.<br>Waarderweg 39, 2031 BN Haarlem, Nederland | EU/1/18/1266 | 6.12.2022 |
| 5.12.2022 | Xarelto | Bayer AG<br>D-51368 Leverkusen, Deutschland | EU/1/08/472 | 6.12.2022 |
| 9.12.2022 | Abevmy | Mylan IRE Healthcare Limited<br>Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland | EU/1/20/1515 | 14.12.2022 |
| 9.12.2022 | Atriance | Sandoz Pharmaceuticals d.d.<br>Verovškova ulica 57, 1000 Ljubljana, Slovenija | EU/1/07/403 | 12.12.2022 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 9.12.2022 | Aybintio | Samsung Bioepis NL B.V.<br>Olof Palmestraat 10, 2616 LR Delft, Nederland | EU/1/20/1454 | 13.12.2022 |
| 9.12.2022 | Bortezomib Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/15/1019 | 15.12.2022 |
| 9.12.2022 | Deferiprone Lipomed | Lipomed GmbH<br>Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland | EU/1/18/1310 | 12.12.2022 |
| 9.12.2022 | Duaklir Genuair | Covis Pharma Europe B.V.<br>Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/14/964 | 12.12.2022 |
| 9.12.2022 | Eklira Genuair | Covis Pharma Europe B.V.<br>Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/12/778 | 14.12.2022 |
| 9.12.2022 | Erleada | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/18/1342 | 12.12.2022 |
| 9.12.2022 | Eylea | Bayer AG<br>D-51368 Leverkusen, Deutschland | EU/1/12/797 | 13.12.2022 |
| 9.12.2022 | Herzuma | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/17/1257 | 14.12.2022 |
| 9.12.2022 | Insulin aspart Sanofi | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/20/1447 | 13.12.2022 |
| 9.12.2022 | Insulin lispro Sanofi | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/17/1203 | 13.12.2022 |
| 9.12.2022 | Onbevzi | Samsung Bioepis NL B.V.<br>Olof Palmestraat 10, 2616 LR Delft, Nederland | EU/1/20/1499 | 13.12.2022 |
| 9.12.2022 | Oyavas | STADA Arzneimittel AG<br>Stadastraße 2-18, 61118 Bad Vilbel, Deutschland | EU/1/20/1510 | 12.12.2022 |
| 9.12.2022 | Qarziba | EUSA Pharma (Netherlands) B.V.<br>Beechavenue 54, 1119PW Schiphol-Rijk, Nederland | EU/1/17/1191 | 14.12.2022 |
| 9.12.2022 | Retsevmo | Eli Lilly Nederland B.V.<br>Papendorpseweg 83, 3528 BJ Utrecht, Nederland | EU/1/20/1527 | 12.12.2022 |
| 9.12.2022 | Riarify | Chiesi Farmaceutici S.p.A.<br>Via Palermo 26/A, 43122 Parma, Italia | EU/1/18/1275 | 12.12.2022 |
| 9.12.2022 | Spravato | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/19/1410 | 12.12.2022 |
| 9.12.2022 | Suliqua | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/16/1157 | 13.12.2022 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 9.12.2022 | Vaxelis | MCM Vaccine B.V.<br>Robert Boyleweg 4, 2333 CG Leiden, Nederland | EU/1/15/1079 | 13.12.2022 |
| 9.12.2022 | Vydura | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/22/1645 | 12.12.2022 |
| 9.12.2022 | Xydalba | AbbVie Deutschland GmbH & Co. KG<br>Knollstrasse, 67061 Ludwigshafen, Deutschland | EU/1/14/986 | 12.12.2022 |
| 9.12.2022 | Zirabev | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/18/1344 | 12.12.2022 |
| 12.12.2022 | Alymsys | Mabxience Research SL<br>C/ Manuel Pombo Angulo 28 – 3a y 4a Planta, 28050 Madrid, España | EU/1/20/1509 | 13.12.2022 |
| 12.12.2022 | Cablivi | Ablynx N.V.<br>Technologiepark 21, 9052 Zwijnaarde, België | EU/1/18/1305 | 21.12.2022 |
| 12.12.2022 | Dificlir | Tillotts Pharma GmbH<br>Warmbacher Strasse 80, 79618 Rheinfelden, Deutschland | EU/1/11/733 | 13.12.2022 |
| 12.12.2022 | DuoPlavin | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/10/619 | 14.12.2022 |
| 12.12.2022 | Dupixent | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/17/1229 | 13.12.2022 |
| 12.12.2022 | Enhertu | Daiichi Sankyo Europe GmbH<br>Zielstattstraße 48, 81379 München, Deutschland | EU/1/20/1508 | 13.12.2022 |
| 12.12.2022 | Karvezide | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/085 | 13.12.2022 |
| 12.12.2022 | Kisqali | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/17/1221 | 13.12.2022 |
| 12.12.2022 | Refixia | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsvaerd, Danmark | EU/1/17/1193 | 13.12.2022 |
| 16.12.2022 | Avastin | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/04/300 | 19.12.2022 |
| 16.12.2022 | Bretaris Genuair | Covis Pharma Europe B.V.<br>Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/12/781 | 3.1.2023 |
| 16.12.2022 | Brilique | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/10/655 | 19.12.2022 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 16.12.2022 | Brimica Genuair | Covis Pharma Europe B.V.<br>Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/14/963 | 19.12.2022 |
| 16.12.2022 | Caprelsa | Genzyme Europe B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/11/749 | 19.12.2022 |
| 16.12.2022 | Ceprotin | Baxter AG<br>Industriestraße 67, 1221 Wien, Österreich | EU/1/01/190 | 19.12.2022 |
| 16.12.2022 | Combivir | ViiV Healthcare BV<br>Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland | EU/1/98/058 | 19.12.2022 |
| 16.12.2022 | Corbilta | Orion Corporation<br>Orionintie 1, 02200 Espoo, Suomi | EU/1/13/859 | 20.12.2022 |
| 16.12.2022 | DUAVIVE | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/14/960 | 20.12.2022 |
| 16.12.2022 | DuoPlavin | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/10/619 | 19.12.2022 |
| 16.12.2022 | Dupixent | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/17/1229 | 19.12.2022 |
| 16.12.2022 | Eptifibatide Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/15/1065 | 19.12.2022 |
| 16.12.2022 | Granpidam | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/16/1137 | 19.12.2022 |
| 16.12.2022 | Imatinib Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/13/845 | 19.12.2022 |
| 16.12.2022 | Imfinzi | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/18/1322 | 19.12.2022 |
| 16.12.2022 | Inhixa | Techdow Pharma Netherlands B.V.<br>Strawinskylaan 1143, Toren C-11, 1077 XX Amsterdam, Nederland | EU/1/16/1132 | 22.12.2022 |
| 16.12.2022 | Intuniv | Takeda Pharmaceuticals International AG Ireland Branch<br>Block 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland | EU/1/15/1040 | 20.12.2022 |
| 16.12.2022 | Iscover | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/070 | 19.12.2022 |
| 16.12.2022 | Iscover | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/070 | 19.12.2022 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 16.12.2022 | Iscover | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/070 | 19.12.2022 |
| 16.12.2022 | Karvea | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/97/049 | 20.12.2022 |
| 16.12.2022 | Levodopa/ Carbidopa/ Entacapone Orion | Orion Corporation<br>Orionintie 1, 02200 Espoo, Suomi | EU/1/11/706 | 21.12.2022 |
| 16.12.2022 | Lynparza | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/14/959 | 19.12.2022 |
| 16.12.2022 | Moventig | Kyowa Kirin Holdings B.V.<br>Bloemlaan 2, 2132 NP Hoofddorp, Nederland | EU/1/14/962 | 21.12.2022 |
| 16.12.2022 | Mvabea | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/20/1445 | 20.12.2022 |
| 16.12.2022 | Myalepta | Amryt Pharmaceuticals DAC<br>45 Mespil Road, Dublin 4, Ireland | EU/1/18/1276 | 21.12.2022 |
| 16.12.2022 | Neulasta | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/02/227 | 20.12.2022 |
| 16.12.2022 | Ocaliva | ADVANZ PHARMA Limited<br>Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland | EU/1/16/1139 | 19.12.2022 |
| 16.12.2022 | Ozawade | Bioprojet Pharma<br>9 rue Rameau, 75002 Paris, France | EU/1/21/1546 | 19.12.2022 |
| 16.12.2022 | Plavix | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/069 | 19.12.2022 |
| 16.12.2022 | Plavix | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/069 | 19.12.2022 |
| 16.12.2022 | Plavix | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/069 | 19.12.2022 |
| 16.12.2022 | Resolor | Takeda Pharmaceuticals International AG Ireland Branch<br>Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland | EU/1/09/581 | 20.12.2022 |
| 16.12.2022 | Rybelsus | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsvaerd, Danmark | EU/1/20/1430 | 20.12.2022 |
| 16.12.2022 | Sarclisa | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/20/1435 | 19.12.2022 |
| 16.12.2022 | Saxenda | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsvaerd, Danmark | EU/1/15/992 | 19.12.2022 |
| 16.12.2022 | Spikevax | MODERNA BIOTECH SPAIN, S.L.<br>Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España | EU/1/20/1507 | 19.12.2022 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 16.12.2022 | Trajenta | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/11/707 | 19.12.2022 |
| 16.12.2022 | Tresiba | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsvaerd, Danmark | EU/1/12/807 | 20.12.2022 |
| 16.12.2022 | Truvelog Mix 30 | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/22/1639 | 19.12.2022 |
| 16.12.2022 | Twynsta | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/10/648 | 3.1.2023 |
| 16.12.2022 | Zoledronic acid Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/13/834 | 19.12.2022 |
| 19.12.2022 | Inrebic | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/20/1514 | 20.12.2022 |
| 20.12.2022 | Ibandronic acid Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/12/798 | 22.12.2022 |
| 20.12.2022 | Mvasi | Amgen Technology (Ireland) UC<br>Pottery Road, Dun Laoghaire, Co. Dublin, Ireland | EU/1/17/1246 | 4.1.2023 |
| 20.12.2022 | Rivaroxaban Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/20/1488 | 22.12.2022 |
| 20.12.2022 | Sarclisa | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/20/1435 | 21.12.2022 |
| 20.12.2022 | Sirturo | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/13/901 | 21.12.2022 |
| 20.12.2022 | Skytrofa | Ascendis Pharma Endocrinology Division A/S<br>Tuborg Boulevard 12, 2900 Hellerup, Danmark | EU/1/21/1607 | 21.12.2022 |
| 22.12.2022 | Comirnaty | BioNTech Manufacturing GmbH<br>An der Goldgrube 12, 55131 Mainz, Deutschland | EU/1/20/1528 | 22.12.2022 |
| 22.12.2022 | Paxlovid | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/22/1625 | 22.12.2022 |

— **Údarú margaíochta a tharraingt siar** (Airteagal 13 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle)

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 5.12.2022 | Trogarzo | Theratechnologies Europe Limited<br>4th Floor, 2 Hume Street, Dublin 2, D02 DV24, Ireland | EU/1/19/1359 | 5.1.2023 |
| 9.12.2022 | NeuroBloc | Sloan Pharma S.a.r.l.<br>33 Rue de Puits Romain, 8070 Bertrange, Luxembourg | EU/1/00/166 | 12.12.2022 |

— **Údarú margaíochta a eisiúint** (Airteagal 38 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle; Airteagal 5 de Rialachán (AE) 2019/6 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

| Dáta an chinnidh | Ainm an táirge íocshláinte | ANI (an tAinm Neamhdhíl-seánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 20.12.2022 | NEOLEISH | Vacsaín leishmaniasis canine (plasmid DNA athchuingreach) | CZ Veterinaria, S.A.<br>La Relva s/n – Torneiros, 36410 Porriño, España | EU/2/22/290 | Nasal spray, solution | Pending | 21.12.2022 |

— **Údarú margaíochta a mhodhnú** (Airteagal 38 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle; Airteagal 5 de Rialachán (AE) 2019/6 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 2.12.2022 | CYTOPOINT | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/17/205 | 5.12.2022 |
| 2.12.2022 | Fevaxyn Pentofel | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/96/002 | 6.12.2022 |
| 2.12.2022 | Solensia | Zoetis Belgium SA<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/20/269 | 5.12.2022 |
| 2.12.2022 | Tulissin | VIRBAC<br>1ère avenue 2065 m LID, 06516 Carros, France | EU/2/20/252 | 6.12.2022 |
| 2.12.2022 | Zenalpha | Vetcare Oy<br>P.O. Box 99, 24101 Salo, Suomi | EU/2/21/279 | 7.12.2022 |
| 9.12.2022 | Convenia | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/06/059 | 14.12.2022 |
| 9.12.2022 | Zeleris | Ceva Santé Animale<br>10 avenue de La Ballastière, 33500 Libourne, France | EU/2/17/210 | 14.12.2022 |
| 13.12.2022 | Innovax-ND-ILT | Intervet International B.V.<br>Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/20/256 | 14.12.2022 |
| 13.12.2022 | Versican Plus DHPPi/L4R | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/14/163 | 14.12.2022 |
| 15.12.2022 | Exzolt | Intervet International B.V.<br>Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/17/212 | 20.12.2022 |
| 15.12.2022 | Librela | Zoetis Belgium SA<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/20/261 | 21.12.2022 |
| 15.12.2022 | NEXGARD SPECTRA | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/14/177 | 16.12.2022 |
| 15.12.2022 | Porcilis PCV M Hyo | Intervet International B.V.<br>Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/14/175 | 20.12.2022 |
| 15.12.2022 | Simparica Trio | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/19/243 | 20.12.2022 |
| 15.12.2022 | Simparica Trio | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/19/243 | 20.12.2022 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 15.12.2022 | UBAC | Laboratorios Hipra, S.A.<br>Avda. La Selva, 135, 17170 Amer (Girona), España | EU/2/18/227 | 21.12.2022 |
| 15.12.2022 | Versican Plus Pi/L4R | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/14/173 | 16.12.2022 |
| 16.12.2022 | Equip WNV | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/08/086 | 20.12.2022 |
| 20.12.2022 | Lydaxx | VETOQUINOL S.A.<br>Magny-Vernois, 70200 Lure, France | EU/2/20/253 | 21.12.2022 |
| 20.12.2022 | Novem | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/04/042 | 22.12.2022 |
| 20.12.2022 | Onsior | Elanco GmbH<br>Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland | EU/2/08/089 | 21.12.2022 |
| 20.12.2022 | ProteqFlu | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/03/037 | 22.12.2022 |
| 20.12.2022 | ProteqFlu-Te | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/03/038 | 22.12.2022 |
| 20.12.2022 | Rabitec | Ceva Santé Animale<br>10 avenue de La Ballastière, 33500 Libourne, France | EU/2/17/219 | 21.12.2022 |
| 20.12.2022 | RHINISENG | Laboratorios Hipra, S.A.<br>Avda. La Selva, 135, 17170 Amer (Girona), España | EU/2/10/109 | 22.12.2022 |
| 20.12.2022 | Suprelorin | VIRBAC S.A.<br>1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France | EU/2/07/072 | 23.12.2022 |
| 20.12.2022 | Tulaven | Ceva Santé Animale<br>10 avenue de La Ballastière, 33500 Libourne, France | EU/2/20/251 | 21.12.2022 |

Aon duine ar mian leis féachaint ar an tuarascáil mheasúnaithe phoiblí maidir leis na táirgí íocshláinte atá i gceist agus na cinntí a bhaineann léi, iarrtar orthu teagmháil a dhéanamh le:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS