ELI: http://data.europa.eu/eli/C/2025/1825/oj

**Achoimre ar chinntí an Aontais Eorpaigh maidir le húdaruithe margaíochta i ndáil le táirgí íocshláinte ó 1 Feabhra 2025 go dtí 28 Feabhra 2025**

*(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])*

(C/2025/1825)

— **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 Neamhdhílseánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 3.2.2025 | HETRONIFLY | serplulimab | Henlius Europe GmbH<br>Sternstraße 67, 40479 Düsseldorf, Deutschland | EU/1/24/1870 | Tiúchán do thuaslagán le haghaidh insilte | L01FF12 | 6.2.2025 |
| 10.2.2025 | ANDEMBRY | garadacimab | CSL Behring GmbH<br>Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland | EU/1/24/1885 | Tuaslagán le haghaidh insteallta | B06AC07 | 12.2.2025 |
| 10.2.2025 | BEYONTTRA | acoramidis | BridgeBio Europe B.V.<br>Weerdestein 97, 1083 GG Amsterdam, Noord-Holland, Nederland | EU/1/24/1906 | Piolla brataithe le scannán | C01EB25 | 11.2.2025 |
| 10.2.2025 | Korjuny | catumaxomab | Lindis Biotech GmbH<br>Zeppelinstraße 4, 82178 Puchheim, Deutschland | EU/1/24/1826 | Tiúchán do thuaslagán le haghaidh insilte | L01FX03 | 12.2.2025 |
| 12.2.2025 | Emcitate | Tírítreacól | Rare Thyroid Therapeutics International AB<br>Klara Norra Kyrkogata 26, 111 22 Stockholm, Sverige | EU/1/24/1897 | Dispersible tablet | H03AA04 | 17.2.2025 |
| 12.2.2025 | Eydenzelt | aflibercept | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/24/1895 | Tuaslagán le haghaidh insteallta | S01LA05 | 18.2.2025 |

[1] IO L 136, 30.4.2004, lch. 1, ELI: https://data.europa.eu/eli/reg/2004/726/oj.
[2] IO L 4, 7.1.2019, lch. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

| Dáta an chinnidh | Ainm an táirge íocshláinte | ANI (an tAinm Neamhdhílseánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 12.2.2025 | Kostaive | zapomeran | Arcturus Therapeutics Europe B.V.<br>Claude Debussylaan 10, 1082 MD Amsterdam, Nederland | EU/1/24/1873 | Powder for dispersion for injection | J07BX03 | 13.2.2025 |
| 12.2.2025 | Nemluvio | nemolizumab | Galderma International<br>La Defense 4, Tour Europlaza, 20 Avenue Andre Prothin, 92927 Paris La Defense Cedex, France | EU/1/24/1901 | Púdar agus tuaslagóir do thuaslagán le haghaidh insteallta | D11AH12 | 13.2.2025 |
| 12.2.2025 | Obodence | denosumab | Samsung Bioepis NL B.V.<br>Olof Palmestraat 10, 2616 LR Delft, Nederland | EU/1/24/1890 | Solution for injection in a pre-filled syringe | M05BX04 | 13.2.2025 |
| 12.2.2025 | WELIREG | belzutifan | Merck Sharp & Dohme B.V.<br>Waarderweg 39, 2031 BN Haarlem, Nederland | EU/1/24/1893 | Piolla brataithe le scannán | L01XX74 | 14.2.2025 |
| 12.2.2025 | Xbryk | denosumab | Samsung Bioepis NL B.V.<br>Olof Palmestraat 10, 2616 LR Delft, Nederland | EU/1/24/1889 | Tuaslagán le haghaidh insteallta | M05BX04 | 13.2.2025 |
| 12.2.2025 | Zefylti | Filgrastim | CuraTeQ Biologics s.r.o<br>Trtinova 260/1, Cakovice, 19600 Prague 9, Česká republika | EU/1/24/1899 | Solution for injection or infusion | L03AA02 | 14.2.2025 |
| 14.2.2025 | Avtozma | tocilizumab | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/24/1896 | Tiúchán do thuaslagán le haghaidh insilte | L04AC07 | 24.2.2025 |
| 14.2.2025 | Osenvelt | Denosumab | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/24/1904 | Tuaslagán le haghaidh insteallta | M05BX04 | 17.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | ANI (an tAinm Neamhdhílseánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 14.2.2025 | Stoboclo | Denosumab | Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/24/1905 | Tuaslagán le haghaidh insteallta | M05BX04 | 21.2.2025 |
| 14.2.2025 | Yesintek | ustekinumab | Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland | EU/1/24/1892 | Tiúchán do thuaslagán le haghaidh insilte Tuaslagán le haghaidh insteallta | L04AC05 | 17.2.2025 |
| 20.2.2025 | Seladelpar Gilead | Seladelpar | Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/24/1898 | Capsúl, crua | A05AX07 | 21.2.2025 |
| 26.2.2025 | Paxneury | guanfacine | Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España | EU/1/24/1908 | Táibléad ar scaoileadh fada | C02AC02 | 4.3.2025 |
| 28.2.2025 | Tuzulby | Methylphenidate hydrochloride | Neuraxpharm Pharmaceuticals S.L. Avinguda De Barcelona 69, Poligono Industrialde La Fuensanta, 08970 Sant Joan Despi, España | EU/1/24/1907 | Prolonged-release chewable tablet | N06BA04 | 3.3.2025 |
| 28.2.2025 | VIMKUNYA | Chikungunya vaccine (recombinant, adsorbed) | Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark | EU/1/25/1916 | Fuaidreán le haghaidh insteallta | Pending | 28.2.2025 |

— **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 |
|---|---|---|---|---|
| 3.2.2025 | Ambrisentan Viatris | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/19/1368 | 5.2.2025 |
| 3.2.2025 | Arsenic trioxide Mylan | Mylan Ireland Limited<br>Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland | EU/1/20/1427 | 5.2.2025 |
| 3.2.2025 | Brintellix | H. Lundbeck A/S<br>Ottiliavej 9, 2500 Valby, Danmark | EU/1/13/891 | 4.2.2025 |
| 3.2.2025 | Catiolanze | Santen Oy<br>Niittyhaankatu 20, 33720 Tampere, Suomi | EU/1/23/1763 | 5.2.2025 |
| 3.2.2025 | Ervebo | Merck Sharp & Dohme B.V.<br>Waarderweg 39, 2031 BN Haarlem, Nederland | EU/1/19/1392 | 4.2.2025 |
| 3.2.2025 | Eucreas | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/07/425 | 4.2.2025 |
| 3.2.2025 | EURneffy | ALK-Abelló A/S, Bøge Allé 6-8, 2970 Hørsholm, Danmark | EU/1/24/1846 | 7.2.2025 |
| 3.2.2025 | Icandra | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/08/484 | 4.2.2025 |
| 3.2.2025 | Kesimpta | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/21/1532 | 6.2.2025 |
| 3.2.2025 | Kinzalkomb | Bayer AG<br>D-51368 Leverkusen, Deutschland | EU/1/02/214 | 4.2.2025 |
| 3.2.2025 | MicardisPlus | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/02/213 | 5.2.2025 |
| 3.2.2025 | Pregabalin Pfizer | Upjohn EESV<br>Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland | EU/1/14/916 | 4.2.2025 |
| 3.2.2025 | Roclanda | Santen Oy<br>Niittyhaankatu 20, 33720 Tampere, Suomi | EU/1/20/1502 | 5.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 3.2.2025 | Ryeqo | Gedeon Richter Plc.<br>Gyömrői út 19-21, 1103 Budapest, Magyarország | EU/1/21/1565 | 6.2.2025 |
| 3.2.2025 | Zeffix | GlaxoSmithKline (Ireland) Limited<br>12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland | EU/1/99/114 | 5.2.2025 |
| 3.2.2025 | Zomarist | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/08/483 | 4.2.2025 |
| 7.2.2025 | Duloxetine Viatris | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/15/1010 | 10.2.2025 |
| 7.2.2025 | Piqray | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/20/1455 | 10.2.2025 |
| 7.2.2025 | Synjardy | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/15/1003 | 5.3.2025 |
| 7.2.2025 | Veoza | Astellas Pharma Europe B.V.<br>Sylviusweg 62, 2333 BE Leiden, Nederland | EU/1/23/1771 | 13.2.2025 |
| 10.2.2025 | Ambrisentan Viatris | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/19/1368 | 12.2.2025 |
| 10.2.2025 | GoResp Digihaler | Teva Pharma B.V.<br>Swensweg 5, 2031GA Haarlem, Nederland | EU/1/19/1403 | 14.2.2025 |
| 10.2.2025 | Jardiance | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/14/930 | 17.2.2025 |
| 10.2.2025 | Ryzodeg | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsvaerd, Danmark | EU/1/12/806 | 12.2.2025 |
| 10.2.2025 | Semglee | Biosimilar Collaborations Ireland Limited<br>Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland | EU/1/18/1270 | 11.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 10.2.2025 | Teysuno | Nordic Group B.V.<br>Siriusdreef 41, 2132 WT Hoofddorp, Nederland | EU/1/11/669 | 13.2.2025 |
| 10.2.2025 | Translarna | PTC Therapeutics International Limited<br>Unit 1, 52-55 Sir John Rogerson's Quay, Dublin 2, D02 NA07, Ireland | EU/1/13/902 | 11.2.2025 |
| 10.2.2025 | Tresiba | Novo Nordisk A/S<br>Novo Alle 1, 2880 Bagsvaerd, Danmark | EU/1/12/807 | 11.2.2025 |
| 10.2.2025 | Xaluprine | Nova Laboratories Ireland Limited<br>3rd Floor, Ulysses House, Foley Street, Dublin 1, Ireland | EU/1/11/727 | 11.2.2025 |
| 12.2.2025 | Advagraf | Astellas Pharma Europe B.V.<br>Sylviusweg 62, 2333 BE Leiden, Nederland | EU/1/07/387 | 13.2.2025 |
| 12.2.2025 | Bemrist Breezhaler | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/20/1441 | 17.2.2025 |
| 12.2.2025 | Casgevy | Vertex Pharmaceuticals (Ireland) Limited<br>Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland | EU/1/23/1787 | 17.2.2025 |
| 12.2.2025 | Envarsus | Chiesi Farmaceutici S.p.A.<br>Via Palermo 26/A, 43122 Parma, Italia | EU/1/14/935 | 13.2.2025 |
| 12.2.2025 | Filspari | Vifor France<br>100–101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France | EU/1/23/1788 | 13.2.2025 |
| 12.2.2025 | Imfinzi | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/18/1322 | 13.2.2025 |
| 12.2.2025 | Nepexto | Biosimilar Collaborations Ireland Limited<br>Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland | EU/1/20/1436 | 14.2.2025 |
| 12.2.2025 | Ofev | Boehringer Ingelheim International GmbH<br>Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland | EU/1/14/979 | 14.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 12.2.2025 | Omvoh | Eli Lilly Nederland B.V.<br>Papendorpseweg 83, 3528 BJ Utrecht, Nederland | EU/1/23/1736 | 13.2.2025 |
| 12.2.2025 | Upstaza | PTC Therapeutics International Limited<br>70 Sir John Rogerson's Quay, Dublin 2, Ireland | EU/1/22/1653 | 14.2.2025 |
| 12.2.2025 | Zimbus Breezhaler | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/20/1440 | 17.2.2025 |
| 14.2.2025 | Arexvy | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, 1330 Rixensart, Belgique | EU/1/23/1740 | 18.2.2025 |
| 14.2.2025 | Atectura Breezhaler | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/20/1439 | 17.2.2025 |
| 14.2.2025 | Avamys | GlaxoSmithKline (Ireland) Limited<br>12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland | EU/1/07/434 | 20.2.2025 |
| 14.2.2025 | Enerzair Breezhaler | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/20/1438 | 17.2.2025 |
| 14.2.2025 | IMJUDO | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/22/1713 | 17.2.2025 |
| 14.2.2025 | Modigraf | Astellas Pharma Europe B.V.<br>Sylviusweg 62, 2333 BE Leiden, Nederland | EU/1/09/523 | 17.2.2025 |
| 14.2.2025 | Mounjaro | Eli Lilly Nederland B.V.<br>Papendorpseweg 83, 3528 BJ Utrecht, Nederland | EU/1/22/1685 | 27.2.2025 |
| 14.2.2025 | Reblozyl | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/20/1452 | 18.2.2025 |
| 14.2.2025 | Tepadina | ADIENNE S.r.l.S.U.<br>Via Galileo Galilei 19, 20867 Caponago (MB), Italia | EU/1/10/622 | 17.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 14.2.2025 | Veklury | Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/20/1459 | 17.2.2025 |
| 14.2.2025 | Zoely | Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland | EU/1/11/690 | 17.2.2025 |
| 20.2.2025 | Bretaris Genuair | Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/12/781 | 24.2.2025 |
| 20.2.2025 | Brimica Genuair | Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/14/963 | 24.2.2025 |
| 20.2.2025 | Cotellic | Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/15/1048 | 24.2.2025 |
| 20.2.2025 | Duaklir Genuair | Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/14/964 | 24.2.2025 |
| 20.2.2025 | Eklira Genuair | Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland | EU/1/12/778 | 24.2.2025 |
| 20.2.2025 | Hemlibra | Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/18/1271 | 21.2.2025 |
| 20.2.2025 | Mekinist | Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/14/931 | 21.2.2025 |
| 20.2.2025 | Sarclisa | Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France | EU/1/20/1435 | 24.2.2025 |
| 20.2.2025 | Sugammadex Piramal | Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland | EU/1/23/1739 | 24.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 20.2.2025 | Uzpruvo | STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland | EU/1/23/1784 | 24.2.2025 |
| 20.2.2025 | Xevudy | GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland | EU/1/21/1562 | 24.2.2025 |
| 21.2.2025 | Dynastat | Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/02/209 | 24.2.2025 |
| 21.2.2025 | Finlee | Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/23/1767 | 24.2.2025 |
| 21.2.2025 | Nimenrix | Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/12/767 | 24.2.2025 |
| 21.2.2025 | Zavesca | Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België | EU/1/02/238 | 24.2.2025 |
| 26.2.2025 | Aripiprazole Mylan Pharma | Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/15/1005 | 27.2.2025 |
| 26.2.2025 | Heplisav B | Dynavax GmbH Eichsfelder Strasse 11, D-40595 Düsseldorf, Deutschland | EU/1/20/1503 | 28.2.2025 |
| 26.2.2025 | Inrebic | Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/20/1514 | 27.2.2025 |
| 26.2.2025 | Lydisilka | Estetra SRL Rue Saint Georges 5-7, 4000 Liège, Belgique | EU/1/21/1548 | 27.2.2025 |
| 26.2.2025 | Natpar | Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland | EU/1/15/1078 | 27.2.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 26.2.2025 | Peyona | Chiesi Farmaceutici S.p.A.<br>Via Palermo 26/A, 43122 Parma, Italia | EU/1/09/528 | 28.2.2025 |
| 26.2.2025 | Pregabalin Zentiva | Zentiva, k.s.<br>U Kabelovny 130, 102 37 Praha 10, Česká republika | EU/1/15/1021 | 28.2.2025 |
| 26.2.2025 | Prolia | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/10/618 | 2.3.2025 |
| 26.2.2025 | Stayveer | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/13/832 | 27.2.2025 |
| 26.2.2025 | Tecartus | Kite Pharma EU B.V.<br>Tufsteen 1, 2132 NT Hoofddorp, Nederland | EU/1/20/1492 | 27.2.2025 |
| 26.2.2025 | Ucedane | Eurocept International B.V.<br>Trapgans 5, 1244 RL Ankeveen, Nederland | EU/1/17/1202 | 5.3.2025 |
| 26.2.2025 | Volibris | GlaxoSmithKline (Ireland) Limited<br>12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland | EU/1/08/451 | 27.2.2025 |
| 26.2.2025 | Voraxaze | SERB SAS<br>40 Avenue George V, 75008 Paris, France | EU/1/21/1586 | 28.2.2025 |
| 28.2.2025 | Bevespi Aerosphere | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/18/1339 | 3.3.2025 |
| 28.2.2025 | Doptelet | Swedish Orphan Biovitrum AB (publ)<br>112 76 Stockholm, Sverige | EU/1/19/1373 | 3.3.2025 |
| 28.2.2025 | Drovelis | Gedeon Richter Plc.<br>Gyömrői út 19-21, 1103 Budapest, Magyarország | EU/1/21/1547 | 5.3.2025 |
| 28.2.2025 | Kymriah | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/18/1297 | 4.3.2025 |
| 28.2.2025 | Litfulo | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/23/1755 | 3.3.2025 |
| 28.2.2025 | OPDIVO | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/15/1014 | 3.3.2025 |

| Dáta an chinnidh | Ainm an táirge íocshláinte | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Dáta an fhógra |
|---|---|---|---|---|
| 28.2.2025 | Ronapreve | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639<br>Grenzach-Wyhlen, Deutschland | EU/1/21/1601 | 3.3.2025 |
| 28.2.2025 | Sivextro | Merck Sharp & Dohme B.V.<br>Waarderweg 39, 2031 BN Haarlem,<br>Nederland | EU/1/15/991 | 3.3.2025 |
| 28.2.2025 | Truqap | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/24/1820 | 3.3.2025 |
| 28.2.2025 | YERVOY | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown<br>Corporate Park 2, D15 T867,<br>Dublin 15, Ireland | EU/1/11/698 | 3.3.2025 |
| 28.2.2025 | Zelboraf | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639<br>Grenzach-Wyhlen, Deutschland | EU/1/12/751 | 3.3.2025 |

— **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 |
|---|---|---|---|---|
| 26.2.2025 | Mycapssa | Amryt Pharmaceuticals DAC<br>45 Mespil Road, Dublin 4, Ireland | EU/1/22/1690 | 3.3.2025 |

— **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 Neamhdhílseánaigh Idirnáisiúnta) | Sealbhóir an údaraithe margaíochta | Uimhir na hiontrála sa Chlár Comhphobail | Foirm chógaisíochta | An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch) | Dáta an fhógra |
|---|---|---|---|---|---|---|---|
| 3.2.2025 | TOLFENAMIC ACID VMD | Aigéad tolfanamach | V.M.D.<br>Hoge Mauw 900, 2370 Arendonk, Belgïe | EU/2/24/329 | Tuaslagán le haghaidh insteallta | QM01AG02 | 4.2.2025 |
| 20.2.2025 | BLUEVAC-3 | Vacsaín víreas gormtheanga (neamhghníomhaithe) | CZ Vaccines S.A.U.<br>A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España | EU/2/24/331 | Fuaidreán le haghaidh insteallta | QI04AA02 | 21.2.2025 |
| 20.2.2025 | Syvazul BTV 3 | vacsaín víreas gormtheanga (neamhghníomhaithe) | Laboratorios Syva S.A<br>C/Marqués de la Ensenada16, 28004 Madrid, España | EU/2/24/332 | Fuaidreán le haghaidh insteallta | QI04AA02 | 21.2.2025 |
| 27.2.2025 | Nobilis Multriva REOm | Reovíreas éanúil, cineál ARV-1, díghníomhaithe, Reovíreas éanúil, cineál ARV-4, díghníomhaithe. | Intervet International B.V.<br>Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/24/333 | Eibleacht le haghaidh insteallta | QI01AA04 | 3.3.2025 |



ELI: http://data.europa.eu/eli/C/2025/1825/oj

— **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 |
|---|---|---|---|---|
| 3.2.2025 | Profender | Vetoquinol S.A.<br>Magny-Vernois, 70200 Lure, France | EU/2/05/054 | 4.2.2025 |
| 14.2.2025 | PREVEXXION RN +HVT+IBD | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/20/255 | 18.2.2025 |
| 20.2.2025 | PREVEXXION RN | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/20/254 | 21.2.2025 |
| 20.2.2025 | PREVEXXION RN +HVT | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/23/302 | 21.2.2025 |
| 20.2.2025 | Vaxxitek HVT + IBD | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/02/032 | 21.2.2025 |
| 27.2.2025 | Newflend ND H9 | Ceva-Phylaxia Co. Ltd.<br>Szállás u. 5, 1107 Budapest, Magyarország | EU/2/23/296 | 3.3.2025 |

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