Il-Ġurnal Uffiċjali tal-Unjoni Ewropea

C/2024/3877

28.6.2024

MT

Is-serje C

# Sommarju ta' deċiżjonijiet tal-Unjoni Ewropea dwar l-awtorizzazzjonijiet għat-tqegħid fis-suq tal-prodotti mediċinali minn 1 Mejju 2024 sa 31 Mejju 2024

*(Ippubblikat skont l-Artikolu 13 jew l-Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill [1] jew L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill [2])*

(C/2024/3877)

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN (Denominazzjoni Internazzjonali Komuni) | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Forma farmaċewtika | Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku) | Data ta' notifika |
|---|---|---|---|---|---|---|---|
| 16.5.2024 | Jubbonti | denosumab | Sandoz GmbH<br>Biochemiestrasse 10, 6250 Kundl, Österreich | EU/1/24/1813 | Soluzzjoni għall-injezzjoni | M05BX04 | 21.5.2024 |
| 16.5.2024 | Omlyclo | Omalizumab | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/24/1817 | Soluzzjoni għall-injezzjoni f'siringa mimlija għal-lest | R03DX05 | 24.5.2024 |
| 17.5.2024 | Awiqli | insulina icodec | Novo Nordisk A/S<br>Novo Alle 1, 2880 Bagsvaerd, Danmark | EU/1/24/1815 | Soluzzjoni għall-injezzjoni f'siringa mimlija għal-lest | A10AE07 | 21.5.2024 |
| 17.5.2024 | FABHALTA | iptacopan | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/24/1802 | Kapsula, iebsa | L04AJ08 | 21.5.2024 |
| 17.5.2024 | Wyost | denosumab | Sandoz GmbH<br>Biochemiestrasse 10, 6250 Kundl, Österreich | EU/1/24/1812 | Soluzzjoni għall-injezzjoni | M05BX04 | 21.5.2024 |
| 27.5.2024 | Lytenava | bevacizumab gamma | Outlook Therapeutics Limited<br>10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland | EU/1/24/1798 | Soluzzjoni għall-injezzjoni | S01LA08 | 28.5.2024 |

[1] ĠU L 136, 30.4.2004, p. 1.
[2] ĠU L 4, 7.1.2019, p. 43.

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN (Denominazzjoni Internazzjonali Komuni) | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Forma farmaċewtika | Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku) | Data ta' notifika |
|---|---|---|---|---|---|---|---|
| 27.5.2024 | Neoatricon | Kloridrat tad-dopamina | BrePco Biopharma Ltd.<br>Suite One, The Avenue, Beacon Court, Sandyford, Dublin D18HX31, Ireland | EU/1/24/1804 | Soluzzjoni għal infużjoni | C01CA04 | 28.5.2024 |
| 29.5.2024 | Agilus | dantrolene sodium hemiheptahydrate | Norgine B.V.<br>Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland | EU/1/24/1805 | Trab għal soluzzjoni għall-injezzjoni | M03CA01 | 30.5.2024 |
| 29.5.2024 | Qalsody | tofersen | Biogen Netherlands B.V.<br>Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland | EU/1/23/1783 | Soluzzjoni għall-injezzjoni | N07XX22 | 3.6.2024 |



ELI: http://data.europa.eu/eli/C/2024/3877/oj

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 6.5.2024 | ASPAVELI | Swedish Orphan Biovitrum AB (publ)<br>112 76 Stockholm, Sverige | EU/1/21/1595 | 7.5.2024 |
| 6.5.2024 | Circadin | RAD Neurim Pharmaceuticals EEC SARL<br>4 rue de Marivaux, 75002 Paris, France | EU/1/07/392 | 7.5.2024 |
| 6.5.2024 | Eliquis | Bristol-Myers Squibb/Pfizer EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland | EU/1/11/691 | 8.5.2024 |
| 6.5.2024 | Epclusa | Gilead Sciences Ireland UC<br>Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/16/1116 | 7.5.2024 |
| 6.5.2024 | Fendrix | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, 1330 Rixensart, Belgique | EU/1/04/299 | 8.5.2024 |
| 6.5.2024 | Kanuma | Alexion Europe SAS<br>103-105 rue Anatole France, 92300 Levallois-Perret, France | EU/1/15/1033 | 7.5.2024 |
| 6.5.2024 | Kisplyx | Eisai GmbH<br>Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland | EU/1/16/1128 | 7.5.2024 |
| 6.5.2024 | Orphacol | THERAVIA<br>16 Rue Montrosier, 92200 Neuilly-sur-Seine, France | EU/1/13/870 | 14.5.2024 |
| 6.5.2024 | VEGZELMA | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/22/1667 | 7.5.2024 |
| 6.5.2024 | Xenical | CHEPLAPHARM Arzneimittel GmbH<br>Ziegelhof 24, 17489 Greifswald, Deutschland | EU/1/98/071 | 8.5.2024 |
| 10.5.2024 | Armisarte | Actavis Group PTC ehf.<br>Dalshraun 1, 220 Hafnarfjörður, Íceland | EU/1/15/1063 | 13.5.2024 |
| 10.5.2024 | Darunavir Mylan | Mylan Pharmaceuticals Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/16/1140 | 13.5.2024 |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 10.5.2024 | Fingolimod Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/20/1450 | 13.5.2024 |
| 10.5.2024 | Lojuxta | Amryt Pharmaceuticals DAC<br>45 Mespil Road, Dublin 4, Ireland | EU/1/13/851 | 15.5.2024 |
| 10.5.2024 | Nilemdo | Daiichi Sankyo Europe GmbH<br>Zielstattstraße 48, 81379 München, Deutschland | EU/1/20/1425 | 13.5.2024 |
| 10.5.2024 | Nustendi | Daiichi Sankyo Europe GmbH<br>Zielstattstraße 48, 81379 München, Deutschland | EU/1/20/1424 | 14.5.2024 |
| 10.5.2024 | PreHevbri | VBI Vaccines B.V.<br>Delflandlaan 1, Queen's Tower Office Number 714, 1062 EA Amsterdam, Nederland | EU/1/22/1641 | 15.5.2024 |
| 10.5.2024 | QUVIVIQ | Idorsia Pharmaceuticals Deutschland GmbH<br>Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland | EU/1/22/1638 | 14.5.2024 |
| 10.5.2024 | Revolade | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/10/612 | 13.5.2024 |
| 10.5.2024 | Thalidomide Lipomed | Lipomed GmbH<br>Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland | EU/1/22/1676 | 13.5.2024 |
| 10.5.2024 | Thyrogen | Sanofi B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/99/122 | 14.5.2024 |
| 10.5.2024 | Trevicta | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/14/971 | 14.5.2024 |
| 10.5.2024 | Tyverb | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/07/440 | 14.5.2024 |
| 15.5.2024 | Comirnaty | BioNTech Manufacturing GmbH<br>An der Goldgrube 12, 55131 Mainz, Deutschland | EU/1/20/1528 | 16.5.2024 |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 16.5.2024 | AMGEVITA | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/16/1164 | 17.5.2024 |
| 16.5.2024 | Bondronat | Atnahs Pharma Netherlands B.V.<br>Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark | EU/1/96/012 | 17.5.2024 |
| 16.5.2024 | Cufence | Univar Solutions B.V.<br>Schouwburgplein 30, Rotterdam, 3012 CL, Nederland | EU/1/19/1365 | 21.5.2024 |
| 16.5.2024 | Giapreza | PAION Deutschland GmbH<br>Heussstraße 25, 52078 Aachen, Deutschland | EU/1/19/1384 | 17.5.2024 |
| 16.5.2024 | IBRANCE | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/16/1147 | 17.5.2024 |
| 16.5.2024 | Imvanex | Bavarian Nordic A/S<br>Philip Heymans Allé 3, DK-2900 Hellerup, Danmark | EU/1/13/855 | 30.5.2024 |
| 16.5.2024 | Lumykras | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/21/1603 | 17.5.2024 |
| 16.5.2024 | NUBEQA | Bayer AG<br>D-51368 Leverkusen, Deutschland | EU/1/20/1432 | 17.5.2024 |
| 16.5.2024 | PecFent | Grünenthal GmbH<br>Zieglerstraße 6, 52078, Aachen, Deutschland | EU/1/10/644 | 22.5.2024 |
| 16.5.2024 | Rinvoq | AbbVie Deutschland GmbH & Co. KG<br>Knollstrasse, 67061 Ludwigshafen, Deutschland | EU/1/19/1404 | 17.5.2024 |
| 16.5.2024 | Rozlytrek | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/20/1460 | 17.5.2024 |
| 16.5.2024 | Rybrevant | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/21/1594 | 17.5.2024 |
| 16.5.2024 | Saphnelo | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/21/1623 | 17.5.2024 |
| 16.5.2024 | Vipidia | Takeda Pharma A/S<br>Delta Park 45, 2665 Vallensbaek Strand, Danmark | EU/1/13/844 | 21.5.2024 |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 16.5.2024 | Xromi | Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland | EU/1/19/1366 | 20.5.2024 |
| 17.5.2024 | Grasustek | Juta Pharma GmbH Gutenbergstr. 13, 24941, Flensburg, Deutschland | EU/1/19/1375 | 23.5.2024 |
| 17.5.2024 | Levetiracetam Actavis | Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland | EU/1/11/713 | 21.5.2024 |
| 17.5.2024 | Methylthioninium chloride Proveblue | Provepharm S.A.S. 22 rue Marc Donadille, 13013 Marseille, France | EU/1/11/682 | 22.5.2024 |
| 17.5.2024 | NUCEIVA | Evolus Pharma B.V. Apollolaan 151, 1077 AR Amsterdam, Nederland | EU/1/19/1364 | 21.5.2024 |
| 17.5.2024 | Oxbryta | Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/21/1622 | 21.5.2024 |
| 17.5.2024 | Qdenga | Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland | EU/1/22/1699 | 21.5.2024 |
| 17.5.2024 | TRISENOX | Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/02/204 | 22.5.2024 |
| 21.5.2024 | Rivaroxaban Accord | Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/20/1488 | 22.5.2024 |
| 22.5.2024 | BEKEMV | Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland | EU/1/23/1727 | 24.5.2024 |
| 22.5.2024 | BiResp Spiromax | Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland | EU/1/14/921 | 28.5.2024 |
| 22.5.2024 | Bosulif | Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/13/818 | 23.5.2024 |
| 22.5.2024 | Buccolam | Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España | EU/1/11/709 | 24.5.2024 |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 22.5.2024 | DuoResp Spiromax | Teva Pharma B.V.<br>Swensweg 5, 2031GA Haarlem, Nederland | EU/1/14/920 | 28.5.2024 |
| 22.5.2024 | Ebilfumin | Actavis Group PTC ehf.<br>Dalshraun 1, 220 Hafnarfjörður, Íceland | EU/1/14/915 | 23.5.2024 |
| 22.5.2024 | 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 | 23.5.2024 |
| 22.5.2024 | EVOTAZ | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/15/1025 | 23.5.2024 |
| 22.5.2024 | Karvezide | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/98/085 | 24.5.2024 |
| 22.5.2024 | Komboglyze | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/11/731 | 24.5.2024 |
| 22.5.2024 | Lytgobi | Taiho Pharma Netherlands B.V.<br>Barbara Strozzilaan 201, 1083 HN Amsterdam, Noord-Holland, Nederland | EU/1/23/1741 | 29.5.2024 |
| 22.5.2024 | Menveo | GSK Vaccines S.r.l.<br>Via Fiorentina 1, 53100 Siena, Italia | EU/1/10/614 | 27.5.2024 |
| 22.5.2024 | Opzelura | Incyte Biosciences Distribution B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/23/1726 | 23.5.2024 |
| 22.5.2024 | Procysbi | Chiesi Farmaceutici S.p.A.<br>Via Palermo 26/A, 43122 Parma, Italia | EU/1/13/861 | 29.5.2024 |
| 22.5.2024 | Ratiograstim | ratiopharm GmbH<br>Graf-Arco-Straße 3, 89079 Ulm, Deutschland | EU/1/08/444 | 3.6.2024 |
| 22.5.2024 | Sialanar | Proveca Pharma Limited<br>2 Dublin Landings, North Wall Quay, Dublin 1, Ireland | EU/1/16/1135 | 23.5.2024 |
| 23.5.2024 | Evrenzo | Astellas Pharma Europe B.V.<br>Sylviusweg 62, 2333 BE Leiden, Nederland | EU/1/21/1574 | 23.5.2024 |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 23.5.2024 | Levetiracetam ratiopharm | ratiopharm GmbH<br>Graf-Arco-Straße 3, 89079 Ulm, Deutschland | EU/1/11/702 | 28.5.2024 |
| 23.5.2024 | Levetiracetam Teva | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/11/701 | 23.5.2024 |
| 23.5.2024 | OPDIVO | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/15/1014 | 23.5.2024 |
| 27.5.2024 | Aimovig | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/18/1293 | 28.5.2024 |
| 27.5.2024 | Camcevi | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/22/1647 | 28.5.2024 |
| 27.5.2024 | Columvi | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/23/1742 | 28.5.2024 |
| 27.5.2024 | Imfinzi | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/18/1322 | 28.5.2024 |
| 27.5.2024 | IMJUDO | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/22/1713 | 28.5.2024 |
| 27.5.2024 | Reyataz | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/03/267 | 28.5.2024 |
| 27.5.2024 | Triumeq | ViiV Healthcare BV<br>Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland | EU/1/14/940 | 28.5.2024 |
| 29.5.2024 | BLINCYTO | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/15/1047 | 26.4.2024 |
| 29.5.2024 | BLINCYTO | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/15/1047 | 30.5.2024 |
| 29.5.2024 | Cerdelga | Sanofi B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/14/974 | 31.5.2024 |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 29.5.2024 | Desloratadine Actavis | Actavis Group PTC ehf.<br>Dalshraun 1, 220 Hafnarfjörður, Íceland | EU/1/11/745 | 1.6.2024 |
| 29.5.2024 | Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva | Zentiva, k.s.<br>U Kabelovny 130, 102 37 Praha 10, Česká republika | EU/1/17/1210 | 30.5.2024 |
| 29.5.2024 | Emtricitabine/ Tenofovir disoproxil Krka | KRKA d d., Novo mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/16/1151 | 30.5.2024 |
| 29.5.2024 | Emtricitabine /Tenofovir disoproxil Krka d.d. | KRKA d d., Novo mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/17/1182 | 6.6.2024 |
| 29.5.2024 | Myocet liposomal | CHEPLAPHARM Arzneimittel GmbH<br>Ziegelhof 24, 17489 Greifswald, Deutschland | EU/1/00/141 | 3.6.2024 |
| 29.5.2024 | Omidria | Rayner Surgical (Ireland) Limited<br>The Mill Enterprise Hub, Newtown Link Road, Drogheda, A92 CD3D, Co. Louth, Ireland | EU/1/15/1018 | 4.6.2024 |
| 29.5.2024 | Pregabalin Sandoz | Sandoz GmbH<br>Biochemiestrasse 10, 6250 Kundl, Österreich | EU/1/15/1011 | 6.6.2024 |

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill; L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN (Denominazzjoni Internazzjonali Komuni) | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Forma farmaċewtika | Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku) | Data ta' notifika |
|---|---|---|---|---|---|---|---|
| 6.5.2024 | Nobilis Multriva RT +IBm+ND+Gm +REOm+EDS | Vaċċin (inattivat) għal metapneumovirus tat-tjur, bronkite infettiva tat-tjur, marda ta' Newcastle, marda bursali infettiva tat-tjur, reovirus tat-tjur u virus tas-sindrome ta' produzzjoni ta' bajd anormali | Intervet International B.V.<br>Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/24/309 | Emulsjoni għall-injezzjoni | QI01AA24 | 8.5.2024 |
| 6.5.2024 | Trilocur | trilostan | Emdoka<br>John Lijsenstraat 16, 2321 Hoogstraten, België | EU/2/24/312 | Suspensjoni Orali | QH02CA01 | 7.5.2024 |
| 6.5.2024 | Trilorale | trilostan | Axience<br>Tour Essor, 14 Rue Scandicci, 93500 Pantin, France | EU/2/24/313 | Suspensjoni Orali | QH02CA01 | 7.5.2024 |
| 10.5.2024 | DIVENCE Tetra | Vaċċin tal-virus taddijarea virali bovina tip 1 u tip 2 (subunità, rikombinanti), il-virus tal-parainfluwenza 3 (inattivat) u tal-virus respiratorju sinċiżjali bovin (ħaj) | Laboratorios Hipra, S.A.<br>Avda. La Selva, 135, 17170 Amer (Girona), España | EU/2/24/310 | Lyophilisate u solvent għal soluzzjoni għall-injezzjoni | Pending | 13.5.2024 |



ELI: http://data.europa.eu/eli/C/2024/3877/oj

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN (Denominazzjoni Internazzjonali Komuni) | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Forma farmaċewtika | Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku) | Data ta' notifika |
|---|---|---|---|---|---|---|---|
| 22.5.2024 | Innovax-ND-H5 | Baromfipestis, madárinfluenza és Marek-betegség vakcina (élő, rekombináns) | Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/24/315 | Konċentrat u solvent għal suspensjoni għal injezzjoni | QI01AD | 23.5.2024 |
| 30.5.2024 | RESPIVAC TRT | Virus tar-rinotrakeite tad-dundjani, ħaj | Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España | EU/2/24/314 | Lajofiliżejt għal suspensjoni | QI01AD01 | 3.6.2024 |

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill; L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 6.5.2024 | Purevax RCP FeLV | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/04/048 | 8.5.2024 |
| 6.5.2024 | RESPIPORC FLU-pan H1N1 | Ceva Santé Animale<br>10 avenue de La Ballastière, 33500 Libourne, France | EU/2/17/209 | 13.5.2024 |
| 6.5.2024 | Suiseng Diff/A | Laboratorios Hipra, S.A.<br>Avda. La Selva, 135, 17170 Amer (Girona), España | EU/2/21/278 | 7.5.2024 |
| 6.5.2024 | Zulvac BTV | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/17/207 | 8.5.2024 |
| 10.5.2024 | ProZinc | Boehringer Ingelheim Vetmedica GmbH<br>55216 Ingelheim am Rhein, Deutschland | EU/2/13/152 | 14.5.2024 |
| 30.5.2024 | Advocate | Elanco Animal Health GmbH<br>Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland | EU/2/03/039 | 3.6.2024 |
| 30.5.2024 | Convenia | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/06/059 | 3.6.2024 |
| 30.5.2024 | Cortavance | VIRBAC S.A.<br>1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France | EU/2/06/069 | 31.5.2024 |
| 30.5.2024 | NEOLEISH | CZ Vaccines S.A.U.<br>A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España | EU/2/22/290 | 3.6.2024 |
| 30.5.2024 | NexGard | Boehringer Ingelheim Vetmedica GmbH<br>55216 Ingelheim am Rhein, Deutschland | EU/2/13/159 | 31.5.2024 |
| 30.5.2024 | Syvazul BTV | Laboratorios Syva S.A<br>C/Marqués de la Ensenada16, 28004 Madrid, España | EU/2/18/231 | 3.6.2024 |
| 30.5.2024 | UpCard | Vétoquinol SA<br>Magny-Vernois, 70200 Lure, France | EU/2/15/184 | 4.6.2024 |
| 30.5.2024 | Vaċċine MS-H | Pharmsure Veterinary Products Europe Limited<br>4 Fitzwilliam Terrace, Strand Road, Bray, WICKLOW A98 T6H6, Ireland | EU/2/11/126 | 31.5.2024 |

— **Sospensjoni ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 45 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill; L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill)

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifika |
|---|---|---|---|---|
| 15.5.2024 | Kexxtone | Elanco GmbH<br>Heinz-Lohmann-Straße 4, 27472<br>Cuxhaven, Deutschland | EU/2/12/145 | 17.5.2024 |

Kull min jixtieq jikkonsulta r-rapport ta' evalwazzjoni pubblika dwar il-prodotti mediċinali kkonċernati u d-deċiżjonijiet marbuta magħhom għandu jikkuntattja lil:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS