ELI: http://data.europa.eu/eli/C/2024/5166/oj

# Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2024. gada 1. jūlijs līdz 2024. gada 31. jūlijs

*(Publicēts saskaņā ar 13. vai 38. pantu Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004 ([1]) vai Eiropas Parlamenta un Padomes Regulas (ES) 2019/6 5. pants ([2]))*

(C/2024/5166)

— **Tirdzniecības atļaujas izsniegšana** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004): **Pieņemtas**

| Lēmuma datums | Zāļu nosaukums | INN (starptautiskais nepatentētais nosaukums) | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Farmaceitiskā forma | AĶT kods (Anatomiski ķīmiski terapeitiskais kods) | Paziņojuma datums |
|---|---|---|---|---|---|---|---|
| 24.7.2024 | Apexelsin | Paklitaksels | *WhiteOak Pharmaceutical B.V. Teleportboulevard 130, Amsterdam, 1043 EJ, Nederland* | EU/1/24/1835 | Pulveris infūziju dispersijas pagatavošanai | L01CD01 | 26.7.2024 |
| 24.7.2024 | Cejemly | sugemalimab | *SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland* | EU/1/24/1833 | Koncentrāts infūziju šķīduma pagatavošanai | L01FF11 | 25.7.2024 |
| 24.7.2024 | DURVEQTIX | fidanakogēna elaparvoveks | *Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België* | EU/1/24/1838 | Koncentrāts infūziju šķīduma pagatavošanai | Pending | 26.7.2024 |
| 24.7.2024 | Kinpeygo | budezonīds | *STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland* | EU/1/22/1657 | Ilgstošās darbības cietās kapsula | A07EA06 | 29.7.2024 |
| 24.7.2024 | Pomalidomide Krka | pomalidomide | *KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija* | EU/1/24/1832 | Cietās kapsulas | L04AX06 | 25.7.2024 |
| 24.7.2024 | Pomalidomide Zentiva | Pomalidomīds | *Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika* | EU/1/24/1830 | Cietās kapsulas | L04AX06 | 25.7.2024 |

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

| Lēmuma datums | Zāļu nosaukums | INN (starptautiskais nepatentētais nosaukums) | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Farmaceitiskā forma | AĶT kods (Anatomiski ķīmiski terapeitiskais kods) | Paziņojuma datums |
|---|---|---|---|---|---|---|---|
| 24.7.2024 | Zegalogue | Dasiglikagona | *Zealand Pharma A/S Sydmarken 11, 2860 Soeborg, Danmark* | EU/1/24/1829 | Šķīdums injekcijai | H04AA02 | 25.7.2024 |
| 26.7.2024 | Avzivi | bevacizumab | *FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland* | EU/1/24/1834 | Koncentrāts infūziju šķīduma pagatavošanai | L01FG01 | 30.7.2024 |
| 26.7.2024 | Dasatinib Accord Healthcare | dasatinib | *Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España* | EU/1/24/1839 | Apvalkotās tabletes | L01EA02 | 29.7.2024 |
| 26.7.2024 | Pomalidomide Accord | pomalidomidum | *Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España* | EU/1/24/1831 | Cietās kapsulas | L04AX06 | 29.7.2024 |

— **Tirdzniecības atļaujas izsniegšana** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004): **Noraidītas**

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 22.7.2024 | Nezglyal | *Minoryx Therapeutics S.L.*<br>*Calle Ernest Lluch 32 Tcm 3, 08302 Mataro, España* | - | 23.7.2024 |

— **Tirdzniecības atļaujas grozīšana** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004): **Pieņemtas**

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 3.7.2024 | Comirnaty | *BioNTech Manufacturing GmbH*<br>*An der Goldgrube 12, 55131 Mainz, Deutschland* | EU/1/20/1528 | 4.7.2024 |
| 5.7.2024 | Aldara | *Viatris Healthcare Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland* | EU/1/98/080 | 8.7.2024 |
| 5.7.2024 | Carbaglu | *Recordati Rare Diseases*<br>*Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France* | EU/1/02/246 | 10.7.2024 |
| 5.7.2024 | Cosentyx | *Novartis Europharm Limited*<br>*Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/14/980 | 8.7.2024 |
| 5.7.2024 | Darunavir Viatris | *Viatris Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/16/1140 | 8.7.2024 |
| 5.7.2024 | Inrebic | *Bristol-Myers Squibb Pharma EEIG*<br>*Plaza 254, Blanchardstown Corporate Park 2, D15T867, Dublin 15, Ireland* | EU/1/20/1514 | 8.7.2024 |
| 5.7.2024 | Iressa | *AstraZeneca AB*<br>*151 85 Södertälje, Sverige* | EU/1/09/526 | 8.7.2024 |
| 5.7.2024 | Jylamvo | *Oresund Pharma ApS*<br>*Orient Plads 1, 2150 Nordhavn, Hovedstaden, Danmark* | EU/1/17/1172 | 8.7.2024 |
| 5.7.2024 | Lonquex | *Teva B.V.*<br>*Swensweg 5, 2031 GA Haarlem, Nederland* | EU/1/13/856 | 8.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 5.7.2024 | Neulasta | *Amgen Europe B.V.*<br>*Minervum 7061, 4817 ZK Breda, Nederland* | EU/1/02/227 | 8.7.2024 |
| 5.7.2024 | NovoMix | *Novo Nordisk A/S*<br>*Novo Allé, 2880 Bagsvaerd, Danmark* | EU/1/00/142 | 8.7.2024 |
| 5.7.2024 | Pergoveris | *Merck Europe B.V.*<br>*Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland* | EU/1/07/396 | 8.7.2024 |
| 5.7.2024 | Ristaben | *Merck Sharp & Dohme B.V.*<br>*Waarderweg 39, 2031 BN Haarlem, Nederland* | EU/1/10/621 | 9.7.2024 |
| 5.7.2024 | Ronapreve | *Roche Registration GmbH*<br>*Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland* | EU/1/21/1601 | 8.7.2024 |
| 5.7.2024 | Saxenda | *Novo Nordisk A/S*<br>*Novo Allé, 2880 Bagsvaerd, Danmark* | EU/1/15/992 | 8.7.2024 |
| 5.7.2024 | Sibnayal | *ADVICENNE*<br>*262, rue du Faubourg Saint Honoré 75008 Paris, France* | EU/1/20/1517 | 8.7.2024 |
| 5.7.2024 | Temozolomide Accord | *Accord Healthcare S.L.U.*<br>*World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España* | EU/1/10/615 | 8.7.2024 |
| 5.7.2024 | Tigecycline Accord | *Accord Healthcare S.L.U.*<br>*World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España* | EU/1/19/1394 | 8.7.2024 |
| 5.7.2024 | TUKYSA | *Pfizer Europe MA EEIG*<br>*Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België* | EU/1/20/1526 | 11.7.2024 |
| 5.7.2024 | ZTALMY | *Marinus Pharmaceuticals Emerald Limited*<br>*10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland* | EU/1/23/1743 | 10.7.2024 |
| 8.7.2024 | Sugammadex Amomed | *AOP Orphan Pharmaceuticals GmbH*<br>*Leopold-Ungar-Platz 2, 1190 Wien, Österreich* | EU/1/22/1708 | 11.7.2024 |
| 8.7.2024 | Tevimbra | *BeiGene Ireland Limited*<br>*10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland* | EU/1/23/1758 | 9.7.2024 |
| 8.7.2024 | Victoza | *Novo Nordisk A/S*<br>*Novo Allé, 2880 Bagsvaerd, Danmark* | EU/1/09/529 | 9.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 12.7.2024 | Ocaliva | *ADVANZ PHARMA Limited Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland* | EU/1/16/1139 | 15.7.2024 |
| 12.7.2024 | Ristfor | *Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland* | EU/1/10/620 | 16.7.2024 |
| 12.7.2024 | Soliris | *Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France* | EU/1/07/393 | 15.7.2024 |
| 17.7.2024 | Accofil | *Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España* | EU/1/14/946 | 18.7.2024 |
| 17.7.2024 | Fluenz | *AstraZeneca AB 151 85 Södertälje, Sverige* | EU/1/24/1816 | 18.7.2024 |
| 17.7.2024 | Galvus | *Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/07/414 | 18.7.2024 |
| 17.7.2024 | GAVRETO | *Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland* | EU/1/21/1555 | 18.7.2024 |
| 17.7.2024 | Minjuvi | *Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland* | EU/1/21/1570 | 18.7.2024 |
| 17.7.2024 | Rekovelle | *Ferring Pharmaceuticals A/S Amager Strandvej 405, 2770 Kastrup, Danmark* | EU/1/16/1150 | 23.7.2024 |
| 17.7.2024 | Ritonavir Viatris | *Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/17/1242 | 18.7.2024 |
| 17.7.2024 | Tepkinly | *AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland* | EU/1/23/1759 | 18.7.2024 |
| 18.7.2024 | Levetiracetam SUN | *Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland* | EU/1/11/741 | 25.7.2024 |
| 18.7.2024 | Retacrit | *Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België* | EU/1/07/431 | 18.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 19.7.2024 | Hyrimoz | *Sandoz GmbH*<br>*Biochemiestrasse 10, 6250 Kundl, Österreich* | EU/1/18/1286 | 22.7.2024 |
| 19.7.2024 | Piqray | *Novartis Europharm Limited*<br>*Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/20/1455 | 22.7.2024 |
| 19.7.2024 | Pregabalin Viatris | *Viatris Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/15/997 | 24.7.2024 |
| 19.7.2024 | Scemblix | *Novartis Europharm Limited*<br>*Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/22/1670 | 22.7.2024 |
| 19.7.2024 | Votrient | *Novartis Europharm Limited*<br>*Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/10/628 | 22.7.2024 |
| 22.7.2024 | Avonex | *Biogen Netherlands B.V.*<br>*Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland* | EU/1/97/033 | 23.7.2024 |
| 22.7.2024 | Byfavo | *PAION Pharma GmbH*<br>*Heussstraße 25, 52078 Aachen, Deutschland* | EU/1/20/1505 | 25.7.2024 |
| 22.7.2024 | Deferasirox Mylan | *Mylan Pharmaceuticals Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/19/1386 | 23.7.2024 |
| 22.7.2024 | Norvir | *AbbVie Deutschland GmbH & Co. KG*<br>*Knollstrasse, 67061 Ludwigshafen, Deutschland* | EU/1/96/016 | 23.7.2024 |
| 22.7.2024 | Slenyto | *RAD Neurim Pharmaceuticals EEC SARL*<br>*4 rue de Marivaux, 75002 Paris, France* | EU/1/18/1318 | 25.7.2024 |
| 22.7.2024 | Teriflunomide Mylan | *Mylan Pharmaceuticals Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/22/1698 | 23.7.2024 |
| 22.7.2024 | VITRAKVI | *Bayer AG*<br>*D-51368 Leverkusen, Deutschland* | EU/1/19/1385 | 23.7.2024 |
| 23.7.2024 | Prometax | *Almirall, S.A.*<br>*Ronda General Mitre, 151, 08022 Barcelona, España* | EU/1/98/092 | 25.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 24.7.2024 | AUBAGIO | *Sanofi Winthrop Industrie*<br>*82 avenue Raspail, 94250 Gentilly, France* | EU/1/13/838 | 25.7.2024 |
| 24.7.2024 | Buvidal | *Camurus AB*<br>*Ideon Science Park, 223 70 Lund, Sverige* | EU/1/18/1336 | 25.7.2024 |
| 24.7.2024 | Bydureon | *AstraZeneca AB*<br>*151 85 Södertälje, Sverige* | EU/1/11/696 | 25.7.2024 |
| 24.7.2024 | Bylvay | *Ipsen Pharma*<br>*65 quai Georges Gorse, 92100 Boulogne-Billancourt, France* | EU/1/21/1566 | 29.7.2024 |
| 24.7.2024 | Caprelsa | *Sanofi B.V.*<br>*Paasheuvelweg 25, 1105 BP Amsterdam, Nederland* | EU/1/11/749 | 25.7.2024 |
| 24.7.2024 | Fluad Tetra | *Seqirus Netherlands B.V.*<br>*Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland* | EU/1/20/1433 | 25.7.2024 |
| 24.7.2024 | Flucelvax Tetra | *Seqirus Netherlands B.V.*<br>*Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland* | EU/1/18/1326 | 25.7.2024 |
| 24.7.2024 | Idefirix | *Hansa Biopharma AB*<br>*P.O. Box 785, 220 07 Lund, Sverige* | EU/1/20/1471 | 25.7.2024 |
| 24.7.2024 | Ilumetri | *Almirall, S.A.*<br>*Ronda General Mitre, 151, 08022 Barcelona, España* | EU/1/18/1323 | 29.7.2024 |
| 24.7.2024 | JCOVDEN | *Janssen-Cilag International NV*<br>*Turnhoutseweg 30, 2340 Beerse, België* | EU/1/20/1525 | 25.7.2024 |
| 24.7.2024 | Kaletra | *AbbVie Deutschland GmbH & Co. KG*<br>*Knollstrasse, 67061 Ludwigshafen, Deutschland* | EU/1/01/172 | 25.7.2024 |
| 24.7.2024 | Leflunomide medac | *medac Gesellschaft für klinische Spezialpräparate mbH*<br>*Theaterstraße 6, 22880 Wedel, Deutschland* | EU/1/10/637 | 25.7.2024 |
| 24.7.2024 | Leflunomide Zentiva | *Zentiva k.s.*<br>*U kabelovny 130, 102 37 Praha 10, Česká republika* | EU/1/09/604 | 29.7.2024 |
| 24.7.2024 | Mvabea | *Janssen-Cilag International NV*<br>*Turnhoutseweg 30, 2340 Beerse, België* | EU/1/20/1445 | 25.7.2024 |
| 24.7.2024 | Nexavar | *Bayer AG*<br>*D-51368 Leverkusen, Deutschland* | EU/1/06/342 | 25.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 24.7.2024 | Pregabalin Viatris | *Viatris Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/15/997 | 25.7.2024 |
| 24.7.2024 | Pyzchiva | *Samsung Bioepis NL B.V.*<br>*Olof Palmestraat 10, 2616 LR Delft, Nederland* | EU/1/24/1801 | 30.7.2024 |
| 24.7.2024 | Skyrizi | *AbbVie Deutschland GmbH & Co. KG*<br>*Knollstrasse, 67061 Ludwigshafen, Deutschland* | EU/1/19/1361 | 25.7.2024 |
| 24.7.2024 | Suboxone | *Indivior Europe Limited*<br>*27 Windsor Place, Dublin 2, D02 DK44, Ireland* | EU/1/06/359 | 25.7.2024 |
| 24.7.2024 | TUKYSA | *Pfizer Europe MA EEIG*<br>*Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België* | EU/1/20/1526 | 30.7.2024 |
| 26.7.2024 | Artesunate Amivas | *Amivas Ireland Ltd*<br>*Suite 5, Second Floor, Station House, Railway Square, Waterford, Ireland* | EU/1/21/1582 | 31.7.2024 |
| 26.7.2024 | AYVAKYT | *Blueprint Medicines (Netherlands) B.V.*<br>*Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland* | EU/1/20/1473 | 29.7.2024 |
| 26.7.2024 | Efficib | *Merck Sharp & Dohme B.V.*<br>*Waarderweg 39, 2031 BN Haarlem, Nederland* | EU/1/08/457 | 29.7.2024 |
| 26.7.2024 | Eliquis | *Bristol-Myers Squibb/Pfizer EEIG*<br>*Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland* | EU/1/11/691 | 29.7.2024 |
| 26.7.2024 | Epidyolex | *Jazz Pharmaceuticals Ireland Ltd*<br>*5th Floor, Waterloo Exchange, Waterloo Road, Dublin D04 E5W7, Ireland* | EU/1/19/1389 | 30.7.2024 |
| 26.7.2024 | Fareston | *Orion Corporation*<br>*Orionintie 1, 02200 Espoo, Suomi* | EU/1/96/004 | 29.7.2024 |
| 26.7.2024 | Imcivree | *Rhythm Pharmaceuticals Netherlands B.V.*<br>*Radarweg 29, 1043 NX Amsterdam, Nederland* | EU/1/21/1564 | 29.7.2024 |
| 26.7.2024 | Imfinzi | *AstraZeneca AB*<br>*151 85 Södertälje, Sverige* | EU/1/18/1322 | 29.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 26.7.2024 | Janumet | *Merck Sharp & Dohme B.V.*<br>*Waarderweg 39, 2031 BN Haarlem, Nederland* | EU/1/08/455 | 29.7.2024 |
| 26.7.2024 | Orladeyo | *Biocryst Ireland Limited*<br>*Block 4, Harcourt Centre, Harcourt Road, Dublin 2, D02 HW77, Ireland* | EU/1/21/1544 | 29.7.2024 |
| 26.7.2024 | Quinsair | *Chiesi Farmaceutici S.p.A.*<br>*Via Palermo 26/A, 43122 Parma, Italia* | EU/1/14/973 | 31.7.2024 |
| 26.7.2024 | Teriflunomide Accord | *Accord Healthcare S.L.U.*<br>*World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España* | EU/1/22/1693 | 29.7.2024 |
| 26.7.2024 | Vabysmo | *Roche Registration GmbH*<br>*Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland* | EU/1/22/1683 | 29.7.2024 |
| 26.7.2024 | Velmetia | *Merck Sharp & Dohme B.V.*<br>*Waarderweg 39, 2031 BN Haarlem, Nederland* | EU/1/08/456 | 29.7.2024 |
| 26.7.2024 | Vumerity | *Biogen Netherlands B.V.*<br>*Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland* | EU/1/21/1585 | 31.7.2024 |
| 26.7.2024 | Zubsolv | *Accord Healthcare S.L.U.*<br>*World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España* | EU/1/17/1233 | 29.7.2024 |
| 29.7.2024 | Atazanavir Viatris | *Viatris Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/16/1091 | 30.7.2024 |
| 29.7.2024 | Jalra | *Novartis Europharm Limited*<br>*Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/08/485 | 1.8.2024 |
| 29.7.2024 | Lopinavir/Ritonavir Viatris | *Viatris Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/15/1067 | 30.7.2024 |
| 29.7.2024 | Myalepta | *Chiesi Farmaceutici S.p.A.*<br>*Via Palermo 26/A, 43122 Parma, Italia* | EU/1/18/1276 | 30.7.2024 |

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 29.7.2024 | Rasagiline Viatris | *Viatris Limited*<br>*Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland* | EU/1/16/1090 | 30.7.2024 |
| 29.7.2024 | Xiliarx | *Novartis Europharm Limited*<br>*Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland* | EU/1/08/486 | 1.8.2024 |

— **Tirdzniecības atļaujas izņemšana no aprites** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004)

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 5.7.2024 | Evicel | *Omrix Biopharmaceuticals N.V.*<br>*Leonardo Da Vincilaan 15, 1831 Diegem, België* | EU/1/08/473 | 8.7.2024 |
| 5.7.2024 | Tizveni | *BeiGene Ireland Limited*<br>*10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland* | EU/1/24/1797 | 10.7.2024 |
| 18.7.2024 | Esmya | *Gedeon Richter Plc.*<br>*Gyömrői út 19-21, 1103 Budapest, Magyarország* | EU/1/12/750 | 18.7.2024 |
| 26.7.2024 | JCOVDEN | *Janssen-Cilag International NV*<br>*Turnhoutseweg 30, 2340 Beerse, België* | EU/1/20/1525 | 29.7.2024 |

— **Tirdzniecības atļaujas izsniegšana** (38. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004; Eiropas Parlamenta un Padomes Regulas (ES) 2019/6 5. pants): **Pieņemtas**

| Lēmuma datums | Zāļu nosaukums | INN (starptautiskais nepatentētais nosaukums) | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Farmaceitiskā forma | AĶT kods (Anatomiski ķīmiski terapeitiskais kods) | Paziņojuma datums |
|---|---|---|---|---|---|---|---|
| 5.7.2024 | Nobilis Multriva RT +IBm+ND+Gm +REOm | Putnu metapneimovīrusa, putnu infekciozā bronhīta vīrusa, Ņūkāslas slimības vīrusa, putnu infekciozās bursālās slimības vīrusa un putnu reovīrusa vakcīna (inaktivēta) | *Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland* | EU/2/24/317 | Emulsija injekcijai | QI01AA26 | 8.7.2024 |
| 17.7.2024 | Nobilis Multriva RT +IBm+ND+EDS | Putnu metapneimovīrusa, infekciozā bronhīta vīrusa, Ņūkāslas slimības vīrusa un olu dēšanas samazināšanās sidroma vīrusa vakcīna, inaktivēta | *Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland* | EU/2/24/316 | Emulsija injekcijai | Pending | 18.7.2024 |

— **Tirdzniecības atļaujas grozīšana** (38. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004; Eiropas Parlamenta un Padomes Regulas (ES) 2019/6 5. pants): **Pieņemtas**

| Lēmuma datums | Zāļu nosaukums | Tirdzniecības atļaujas turētājs | Ieraksta numurs Kopienas reģistrā | Paziņojuma datums |
|---|---|---|---|---|
| 5.7.2024 | Felpreva | *Vetoquinol S.A.*<br>*Magny-Vernois, 70200 Lure, France* | EU/2/21/277 | 8.7.2024 |
| 5.7.2024 | Forceris | *Ceva Santé Animale*<br>*10 avenue de La Ballastière, 33500 Libourne, France* | EU/2/19/235 | 8.7.2024 |
| 5.7.2024 | Isemid | *Ceva Santé Animale*<br>*10 avenue de La Ballastière, 33500 Libourne, France* | EU/2/18/232 | 9.7.2024 |
| 5.7.2024 | Nobivac LoVo L4 | *Intervet International B.V.*<br>*Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland* | EU/2/23/304 | 8.7.2024 |
| 5.7.2024 | Vectra 3D | *Ceva Santé Animale*<br>*10 avenue de La Ballastière, 33500 Libourne, France* | EU/2/13/156 | 8.7.2024 |
| 5.7.2024 | Vectra Felis | *Ceva Santé Animale*<br>*10 avenue de La Ballastière, 33500 Libourne, France* | EU/2/14/165 | 8.7.2024 |
| 5.7.2024 | Virbagen Omega | *VIRBAC*<br>*1ère Avenue - 2065m – L.I.D., 06516 CARROS, France* | EU/2/01/030 | 8.7.2024 |
| 8.7.2024 | Circovac | *CEVA-Phylaxia Co. Ltd*<br>*Szállás u. 5, 1107 Budapest, Magyarország* | EU/2/07/075 | 10.7.2024 |
| 8.7.2024 | HorStem | *EquiCord S.L*<br>*103-D Loeches, Polígono. Industrial Ventorro del Cano, Alcorcón, 28925 Madrid, España.* | EU/2/18/226 | 11.7.2024 |
| 11.7.2024 | BLUEVAC BTV | *CZ Vaccines S.A.U.*<br>*A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España* | EU/2/11/122 | 12.7.2024 |
| 11.7.2024 | Porcilis AR-T DF | *Intervet International B.V.*<br>*Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland* | EU/2/00/026 | 12.7.2024 |

Ikvienam, kurš vēlas apskatīt publisko novērtējuma ziņojumu par attiecīgajām zālēm un ar tām saistītos lēmumus, jāsazinās ar:

*European Medicines Agency*
*Domenico Scarlattilaan 6*
*1083 HS Amsterdam*
*NETHERLANDS*