C/2024/2197

27.3.2024.

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2024. gada 1. februāra līdz 2024. gada 29. februārim

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

(C/2024/2197)

([1]) OV L 136, 30.4.2004., 1. lpp.
([2]) OV L 4, 7.1.2019., 43. lpp.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. 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
9.2.2024.	Casgevy	eksagamglogēna autotemcels, exagamglogene autotemcel	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/23/1787	Dispersijas infūzijai	B06AX	12.2.2024.
9.2.2024.	Mevlyq	eribulīns	YES Pharmaceutical Development Services GmbH Basler Strasse 7, 61352 Bad Homburg, Deutschland	EU/1/23/1789	Šķīdums injekcijai	L01XX41	13.2.2024.
9.2.2024.	Skyclarys	omaveloksolons	Reata Ireland Limited Block A, George's Quay Plaza, George's Quay, Dublin 2, D02 E440, Ireland	EU/1/23/1786	Cietās kapsulas	Pending	12.2.2024.
16.2.2024.	Ibuprofen Gen.Orph	ibuprofēna	Gen.Orph 185 Bureaux de la Colline, 92213 Saint Cloud Cedex, France	EU/1/23/1791	Šķīdums injekcijai	C01EB16	21.2.2024.
16.2.2024.	Pomalidomide Viatris	pomalidomide	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1785	Cietās kapsulas	L04AX06	19.2.2024.
16.2.2024.	Velsipity	etrazimoda	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1790	Apvalkotās tabletes	L04AE05	19.2.2024.
19.2.2024.	Dabigatran etexilate Leon Farma	dabigatran etexilate	Laboratorios Leon Farma S.A. C/ La Vallina s/n, Poligono Industrial Navatejera, 24193 Villaquilambre León, España	EU/1/23/1769	Cietās kapsulas	B01AE07	21.2.2024.

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
22.2.2024.	Holoclar	Ex vivo audzētas autologās cilvēka radzenes epitēlija šūnas, kas satur cilmes šūnas	Holostem S.r.l. Via Glauco Gottardi 100, 41125 Modena, Italia	EU/1/14/987	Dzīvo audu ekvivalents	S01XA19	23.2.2024.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
1.2.2024.	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	5.2.2024.
1.2.2024.	Hexacima	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/13/828	5.2.2024.
1.2.2024.	Hexyon	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/13/829	2.2.2024.
1.2.2024.	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	3.2.2024.
1.2.2024.	Mirvaso	Galderma International Tour Europlaza, 20 avenue André Prothin, La Défense 4, La Défense Cedex 92927, France	EU/1/13/904	6.2.2024.
1.2.2024.	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/08/448	5.2.2024.
1.2.2024.	Simponi	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/09/546	6.2.2024.
1.2.2024.	Tafinlar	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/865	2.2.2024.
1.2.2024.	Thiotepa Riemser	Esteve Pharmaceuticals GmbH Hohenzollerndamm 150-151, 14199 Berlin, Deutschland	EU/1/21/1536	5.2.2024.
1.2.2024.	Tybost	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/872	5.2.2024.
6.2.2024.	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	7.2.2024.
6.2.2024.	Cegfila	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/19/1409	7.2.2024.
6.2.2024.	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1040	8.2.2024.
6.2.2024.	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	7.2.2024.
6.2.2024.	Nyxoid	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/17/1238	7.2.2024.
6.2.2024.	Sixmo	L. Molteni & C. dei F.lli Alitti Società di . Esercizio .S.p.A Strada Statale 67, Loc. Granatieri, 50018 Scandicci (Firenze), Italia	EU/1/19/1369	7.2.2024.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
6.2.2024.	SomaKit TOC	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/16/1141	8.2.2024.
8.2.2024.	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	9.2.2024.
8.2.2024.	Coagadex	BPL Bioproducts Laboratory GmbH Dornhofstrasse 34, 63263 Neu-Isenburg, Deutschland	EU/1/16/1087	12.2.2024.
8.2.2024.	Dynastat	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/209	9.2.2024.
8.2.2024.	QINLOCK	Deciphera Pharmaceuticals (Netherlands) B.V. Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland	EU/1/21/1569	12.2.2024.
8.2.2024.	Scintimun	CIS bio international Boîte Postale 32, 91192 Gif-sur-Yvette, France	EU/1/09/602	9.2.2024.
8.2.2024.	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	9.2.2024.
8.2.2024.	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	9.2.2024.
8.2.2024.	Zypadhera	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/08/479	9.2.2024.
8.2.2024.	Zyprexa	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/96/022	9.2.2024.
8.2.2024.	Zyprexa Velotab	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/99/125	9.2.2024.
9.2.2024.	Clopidogrel Krka d. d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	12.2.2024.
9.2.2024.	Doptelet	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/19/1373	14.2.2024.
9.2.2024.	DuoPlavin	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/10/619	12.2.2024.
9.2.2024.	Esperoct	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/19/1374	12.2.2024.
9.2.2024.	Protopic	Leo Pharma A/S Industriparken 55, 2750 Ballerup, Danmark	EU/1/02/201	13.2.2024.
9.2.2024.	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	12.2.2024.
9.2.2024.	Translarna	PTC Therapeutics International Limited 5th Floor, 3 Grand Canal Plaza, Grand Canal Street Upper, Dublin 4, D04 EE70, Ireland	EU/1/13/902	12.2.2024.
9.2.2024.	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	15.2.2024.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
16.2.2024.	Arixtra	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/02/206	19.2.2024.
16.2.2024.	Azopt	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/00/129	19.2.2024.
16.2.2024.	Baqsimi	Amphastar France Pharmaceuticals Usine Saint Charles, Eragny Sur Epte, 60590 France	EU/1/19/1406	20.2.2024.
16.2.2024.	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	19.2.2024.
16.2.2024.	Bylvay	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/21/1566	19.2.2024.
16.2.2024.	Cayston	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/09/543	19.2.2024.
16.2.2024.	Entyvio	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/14/923	19.2.2024.
16.2.2024.	Evoltra	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/334	19.2.2024.
16.2.2024.	Fetcroja	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/20/1434	19.2.2024.
16.2.2024.	Hemlibra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/18/1271	20.2.2024.
16.2.2024.	Herzuma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/17/1257	19.2.2024.
16.2.2024.	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	19.2.2024.
16.2.2024.	IMJUDO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1713	19.2.2024.
16.2.2024.	Imraldi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/17/1216	21.2.2024.
16.2.2024.	Jylamvo	Therakind (Europe) Limited Paramount Court, Corrig Road, Sandyford Business Park, Dublin 18, D18 R9C7, Ireland	EU/1/17/1172	27.2.2024.
16.2.2024.	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/20/1468	19.2.2024.
16.2.2024.	Lupkynis	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	20.2.2024.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
16.2.2024.	LysaKare	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/19/1381	19.2.2024.
16.2.2024.	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	19.2.2024.
16.2.2024.	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	21.2.2024.
16.2.2024.	Pregabalin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/15/1027	19.2.2024.
16.2.2024.	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	19.2.2024.
16.2.2024.	Senshio	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/14/978	19.2.2024.
16.2.2024.	Stayveer	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/832	19.2.2024.
16.2.2024.	Stocrin	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/99/111	19.2.2024.
16.2.2024.	Truvada	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/04/305	19.2.2024.
16.2.2024.	Viread	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/01/200	19.2.2024.
16.2.2024.	Vydura	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1645	19.2.2024.
16.2.2024.	Xagrid	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/04/295	19.2.2024.
22.2.2024.	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	27.2.2024.
22.2.2024.	Docetaxel Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/769	26.2.2024.
22.2.2024.	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	26.2.2024.
22.2.2024.	Pravafenix	LABORATOIRES SMB SA 26-28 rue de la Pastorale / 26-28 Herdersliedstraat, 1080 Brussel/Bruxelles, Belgique/België	EU/1/11/679	23.2.2024.
22.2.2024.	Skytrofa	Ascendis Pharma Endocrinology Division A/S Tuborg Boulevard 12, 2900 Hellerup, Danmark	EU/1/21/1607	23.2.2024.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
22.2.2024.	Spectrila	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/15/1072	26.2.2024.
22.2.2024.	Strensiq	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1015	26.2.2024.
22.2.2024.	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	23.2.2024.
23.2.2024.	BLENREP	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/20/1474	29.2.2024.
26.2.2024.	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	28.2.2024.
29.2.2024.	Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/12/802	1.3.2024.
29.2.2024.	Posaconazole AHCL	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1380	1.3.2024.
29.2.2024.	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	1.3.2024.
29.2.2024.	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/08/445	4.3.2024.
29.2.2024.	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	1.3.2024.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
1.2.2024.	Sustiva	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/99/110	3.2.2024.
9.2.2024.	Apealea	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/18/1292	14.2.2024.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
1.2.2024.	Solensia	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	2.2.2024.
1.2.2024.	Solensia	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	2.2.2024.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
1.2.2024.	Zactran	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/08/082	6.2.2024.
29.2.2024.	Metacam	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/97/004	1.3.2024.
29.2.2024.	REXXOLIDE	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/20/263	6.3.2024.

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