IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2023. gada 1. februāra līdz 2023. gada 28. 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)

(2023/C 118/01)

[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
15.2.2023.	Dimethyl Fumarate Accord	dimetilfumarāta	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1711	Zarnās šķīstošās cietās kapsulas	L04AX07	17.2.2023.
20.2.2023.	Hemgenix	etranakogēna dezaparvoveks	CSL Behring GmbH D-35041 Marburg, Deutschland	EU/1/22/1715	Koncentrāts infūziju šķīduma pagatavošanai	B06	23.2.2023.
20.2.2023.	IMJUDO	tremelimumabs	AstraZeneca AB Forskargatan 18, 151 85 Södertälje, Sverige	EU/1/22/1713	Koncentrāts infūziju šķīduma pagatavošanai	L01FX20	23.2.2023.
20.2.2023.	Tremelimumab AstraZeneca	tremelimumabs	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1712	Koncentrāts infūziju šķīduma pagatavošanai	L01FX20	21.2.2023.
24.2.2023.	Paxlovid	Nirmatrelvīrs / ritonavīrs	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	Apvalkotās tabletes	J05AE30	27.2.2023.

— **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
3.2.2023.	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/02/224	6.2.2023.
3.2.2023.	Bortezomib Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1114	6.2.2023.
3.2.2023.	Copiktra	Secura Bio Limited 32 Molesworth Street, Dublin 2 D02 Y512, Co. Dublin, Ireland	EU/1/21/1542	17.2.2023.
3.2.2023.	Darunavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	7.2.2023.
3.2.2023.	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1025	6.2.2023.
3.2.2023.	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	6.2.2023.
3.2.2023.	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	7.2.2023.
3.2.2023.	HALAVEN	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/11/678	8.2.2023.
3.2.2023.	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	17.2.2023.
3.2.2023.	Invanz	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/02/216	9.2.2023.
3.2.2023.	KANJINTI	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/18/1281	6.2.2023.
3.2.2023.	Levetiracetam Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/712	6.2.2023.
3.2.2023.	Nimvastid	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/525	14.2.2023.
3.2.2023.	NULIBRY	Zydus France S.A.S. Zac Les Hautes Patures, 25 Rue Des Peupliers, 92000 Nanterre, France	EU/1/22/1684	9.2.2023.
3.2.2023.	Orencia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/389	6.2.2023.
3.2.2023.	Pemetrexed Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1071	7.2.2023.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
3.2.2023.	Quofenix	A. Menarini – Industrie Farmaceutiche Riunite – s.r.l. Via Sette Santi 3, 50131 Florence, Italia	EU/1/19/1393	8.2.2023.
3.2.2023.	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	13.2.2023.
3.2.2023.	Rixubis	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/14/970	9.2.2023.
3.2.2023.	SCENESSE	Clinuvel Europe Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/14/969	7.2.2023.
3.2.2023.	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	6.2.2023.
3.2.2023.	TRISENOX	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/02/204	7.2.2023.
3.2.2023.	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	6.2.2023.
3.2.2023.	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	6.2.2023.
6.2.2023.	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	7.2.2023.
6.2.2023.	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	7.2.2023.
6.2.2023.	Hefiya	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1287	7.2.2023.
6.2.2023.	Kerendia	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/21/1616	7.2.2023.
6.2.2023.	Tivicay	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/13/892	7.2.2023.
6.2.2023.	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	13.2.2023.
9.2.2023.	AMGLIDIA	AMMTeK 55 rue de Turbigo, 75003 Paris, France	EU/1/18/1279	14.2.2023.
9.2.2023.	Brukinsa	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/21/1576	10.2.2023.
9.2.2023.	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	13.2.2023.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
15.2.2023.	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	17.2.2023.
15.2.2023.	Fulphila	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1329	16.2.2023.
15.2.2023.	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	20.2.2023.
15.2.2023.	JEMPERLI	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	20.2.2023.
15.2.2023.	Lokelma	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1173	16.2.2023.
15.2.2023.	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	16.2.2023.
15.2.2023.	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	20.2.2023.
15.2.2023.	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	6.3.2023.
15.2.2023.	Semglee	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1270	16.2.2023.
15.2.2023.	Trodelvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/21/1592	16.2.2023.
15.2.2023.	Vyndaqel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/11/717	16.2.2023.
15.2.2023.	Zonegran	Amdipharm Limited 3 Burlington Road, Dublin 4, D04 RD68, IRELAND	EU/1/04/307	21.2.2023.
20.2.2023.	Aimovig	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1293	22.2.2023.
20.2.2023.	Calquence	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1479	21.2.2023.
20.2.2023.	Tractocile	Ferring Pharmaceuticals A/S Amager Strandvej 405, 2770 Kastrup, Danmark	EU/1/99/124	3.3.2023.
20.2.2023.	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	21.2.2023.
20.2.2023.	Yuflyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/20/1513	21.2.2023.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
23.2.2023.	Atosiban SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/13/852	27.2.2023.
23.2.2023.	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	24.2.2023.
23.2.2023.	Ivabradine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/17/1190	24.2.2023.
23.2.2023.	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	24.2.2023.
23.2.2023.	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090	2.3.2023.
23.2.2023.	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	24.2.2023.
23.2.2023.	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	24.2.2023.
24.2.2023.	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	27.2.2023.
24.2.2023.	Emselex	zr pharma& GmbH Hietzinger Hauptstrasse 37, 1130 Wien, Österreich	EU/1/04/294	1.3.2023.
24.2.2023.	Febuxostat Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	27.2.2023.
24.2.2023.	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	27.2.2023.
24.2.2023.	QINLOCK	Deciphera Pharmaceuticals (Netherlands) B.V. Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland	EU/1/21/1569	3.3.2023.
24.2.2023.	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	27.2.2023.
24.2.2023.	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	27.2.2023.
24.2.2023.	Ronapreve	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1601	28.2.2023.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
24.2.2023.	TUKYSA	Seagen B.V. Evert van de Beekstraat 1-104, 1118CL Schiphol, Nederland	EU/1/20/1526	2.3.2023.
24.2.2023.	Wakix	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/15/1068	27.2.2023.
27.2.2023.	Abilify	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/04/276	7.3.2023.
27.2.2023.	Aflunov	Seqirus S.r.l. Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italy	EU/1/10/658	28.2.2023.
27.2.2023.	Daptomycin Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1175	28.2.2023.
27.2.2023.	Foclivia	Seqirus S.r.l., Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italia	EU/1/09/577	28.2.2023.
27.2.2023.	NUBEQA	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/20/1432	28.2.2023.
27.2.2023.	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	28.2.2023.
27.2.2023.	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	28.2.2023.
27.2.2023.	Sprycel	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/06/363	28.2.2023.
27.2.2023.	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	28.2.2023.
27.2.2023.	Venclyxto	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/16/1138	28.2.2023.
27.2.2023.	Voriconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/835	28.2.2023.

— **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
23.2.2023.	Pregabalin Zentiva k.s	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1166	24.2.2023.

— **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
2.2.2023.	Tulissin	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/20/252	6.2.2023.
3.2.2023.	Forceris	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/19/235	6.2.2023.
3.2.2023.	Locatim	Biokema Europe Centre des Affaires des Lilas, 77 Avenue des Lilas, 64000 Pau, France	EU/2/99/011	9.2.2023.
3.2.2023.	Panacur AquaSol	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/135	7.2.2023.
6.2.2023.	Apoquel	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	7.2.2023.
6.2.2023.	CLYNAV	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/16/197	7.2.2023.
6.2.2023.	Procox	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/11/123	8.2.2023.
6.2.2023.	Procox	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/11/123	7.2.2023.
6.2.2023.	Versican Plus DHPPi/L4R	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/163	7.2.2023.
9.2.2023.	MiPet Easecto	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/220	14.2.2023.
20.2.2023.	Advocate	Bayer Animal Health GmbH D-51368 Leverkusen, Deutschland	EU/2/03/039	22.2.2023.
20.2.2023.	Bovela	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/176	22.2.2023.
20.2.2023.	GALLIPRANT	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/221	21.2.2023.
20.2.2023.	Suvaxyn Circo + MH RTU	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/15/190	23.2.2023.
23.2.2023.	Locatim	Biokema Europe Centre des Affaires des Lilas, 77 Avenue des Lilas, 64000 Pau, France	EU/2/99/011	1.3.2023.

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

European Medicines Agency
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