ELI: http://data.europa.eu/eli/C/2026/402/oj

Eiropas Savienības Oficiālais Vēstnesis
LV
C sērija
30.1.2026.
C/2026/402

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2025. gada 1. decembris līdz 2025. gada 31. decembris

(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/2026/402)

— **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
22.12.2025.	WAYRILZ	Rilzabrutinibs	*Sanofi B.V.* *Paasheuvelweg 25, 1105 BP* *Amsterdam, Nederland*	EU/1/25/1974	Apvalkotās tabletes	Pending	23.12.2025.

([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.

— **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
4.12.2025.	alli	*Haleon Ireland Dungarvan Limited Knockbrack,Dungarvan, Co. Waterford, Ireland*	EU/1/07/401	5.12.2025.
4.12.2025.	AQUIPTA	*AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland*	EU/1/23/1750	5.12.2025.
4.12.2025.	Beovu	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/19/1417	5.12.2025.
4.12.2025.	Colobreathe	*Essential Pharma Limited Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara CBD 1070, Malta*	EU/1/11/747	17.12.2025.
4.12.2025.	Gazyvaro	*Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland*	EU/1/14/937	5.12.2025.
4.12.2025.	Ibandronic acid Accord	*Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España*	EU/1/12/798	5.12.2025.
4.12.2025.	Lenalidomide Krka	*KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija*	EU/1/20/1519	5.12.2025.
4.12.2025.	NULIBRY	*TMC Pharma (EU) Limited 7a Durands Court, 45 Parnell Street, Waterford, Co. Waterford, X91 P381, Ireland*	EU/1/22/1684	5.12.2025.
4.12.2025.	Rivastigmine Sandoz	*Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich*	EU/1/09/599	9.12.2025.
4.12.2025.	Ronapreve	*Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland*	EU/1/21/1601	5.12.2025.
4.12.2025.	Tauvid	*Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/24/1799	8.12.2025.
4.12.2025.	Triumeq	*ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland*	EU/1/14/940	9.12.2025.
4.12.2025.	Xolair	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/05/319	5.12.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
5.12.2025.	Aimovig	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/18/1293	8.12.2025.
5.12.2025.	Lyvdelzi	*Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland*	EU/1/24/1898	8.12.2025.
5.12.2025.	Palforzia	*STALLERGENES 6 rue Alexis de Tocqueville, 92160 Antony, France*	EU/1/20/1495	15.12.2025.
5.12.2025.	Pregabalin Sandoz	*Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich*	EU/1/15/1011	9.12.2025.
5.12.2025.	Soliris	*Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France*	EU/1/07/393	8.12.2025.
8.12.2025.	AUGTYRO	*Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland*	EU/1/24/1883	11.12.2025.
12.12.2025.	ABSIMKY	*Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España*	EU/1/24/1880	15.12.2025.
12.12.2025.	ALTUVOCT	*Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige*	EU/1/24/1824	15.12.2025.
12.12.2025.	Arsenic Trioxide Accord	*Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España*	EU/1/19/1398	15.12.2025.
12.12.2025.	Biktarvy	*Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland*	EU/1/18/1289	17.12.2025.
12.12.2025.	Cystadane	*Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France*	EU/1/06/379	15.12.2025.
12.12.2025.	DuoTrav	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/06/338	15.12.2025.
12.12.2025.	Enurev Breezhaler	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/12/789	15.12.2025.
12.12.2025.	Exelon	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/98/066	15.12.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
12.12.2025.	Naglazyme	*BioMarin International Limited Shanbally, Ringaskiddy, County Cork P43 R298, Ireland*	EU/1/05/324	16.12.2025.
12.12.2025.	Onbrez Breezhaler	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/09/593	15.12.2025.
12.12.2025.	Qaialdo	*Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/ Rhein, Deutschland*	EU/1/23/1731	16.12.2025.
12.12.2025.	Retsevmo	*Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/20/1527	15.12.2025.
12.12.2025.	Saphnelo	*AstraZeneca AB 151 85 Södertälje, Sverige*	EU/1/21/1623	15.12.2025.
12.12.2025.	Seffalair Spiromax	*Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland*	EU/1/21/1533	18.12.2025.
12.12.2025.	Voydeya	*Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France*	EU/1/24/1792	15.12.2025.
15.12.2025.	Lynparza	*AstraZeneca AB 151 85 Södertälje, Sverige*	EU/1/14/959	16.12.2025.
15.12.2025.	Minjuvi	*Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland*	EU/1/21/1570	16.12.2025.
15.12.2025.	Vedrop	*Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France*	EU/1/09/533	17.12.2025.
15.12.2025.	Yesafili	*Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland*	EU/1/23/1751	16.12.2025.
16.12.2025.	Hefiya	*Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich*	EU/1/18/1287	17.12.2025.
18.12.2025.	Abiraterone Krka	*KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija*	EU/1/21/1553	5.1.2026.
18.12.2025.	Afqlir	*Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich*	EU/1/24/1867	22.12.2025.
18.12.2025.	Alymsys	*Mabxience Research SL C/ Manuel Pombo Angulo 28, 28050 Madrid, España*	EU/1/20/1509	20.12.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
18.12.2025.	Amsparity	*Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België*	EU/1/19/1415	19.12.2025.
18.12.2025.	Avastin	*Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland*	EU/1/04/300	19.12.2025.
18.12.2025.	Avzivi	*FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland*	EU/1/24/1834	19.12.2025.
18.12.2025.	Aybintio	*Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland*	EU/1/20/1454	22.12.2025.
18.12.2025.	Farydak	*pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich*	EU/1/15/1023	19.12.2025.
18.12.2025.	Inrebic	*Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland*	EU/1/20/1514	19.12.2025.
18.12.2025.	Lyxumia	*Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France*	EU/1/12/811	19.12.2025.
18.12.2025.	M-M-RVAXPRO	*Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland*	EU/1/06/337	19.12.2025.
18.12.2025.	Nexium Control	*Haleon Ireland Dungarvan Limited Knockbrack,Dungarvan, Co. Waterford, Ireland*	EU/1/13/860	19.12.2025.
18.12.2025.	Oyavas	*STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland*	EU/1/20/1510	19.12.2025.
18.12.2025.	Pedea	*Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France*	EU/1/04/284	19.12.2025.
18.12.2025.	Rivastigmine 1 A Pharma	*1 A Pharma GmbH Industriestraße 18, 83607 Holzkirchen, Deutschland*	EU/1/09/585	19.12.2025.
18.12.2025.	Shingrix	*GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique*	EU/1/18/1272	19.12.2025.
18.12.2025.	Tremfya	*Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België*	EU/1/17/1234	19.12.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
18.12.2025.	Vegzelma	*Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország*	EU/1/22/1667	22.12.2025.
18.12.2025.	VEYVONDI	*Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich*	EU/1/18/1298	19.12.2025.
18.12.2025.	Vyloy	*Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland*	EU/1/24/1856	19.12.2025.
18.12.2025.	XALKORI	*Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België*	EU/1/12/793	19.12.2025.
18.12.2025.	Xerava	*PAION Pharma GmbH Heussstraße 25, 52078 Aachen, Deutschland*	EU/1/18/1312	24.12.2025.
18.12.2025.	Zirabev	*Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België*	EU/1/18/1344	19.12.2025.
19.12.2025.	Abevmy	*Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland*	EU/1/20/1515	23.12.2025.
19.12.2025.	Abiraterone Accord	*Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España*	EU/1/20/1512	22.12.2025.
19.12.2025.	Aldurazyme	*Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland*	EU/1/03/253	22.12.2025.
19.12.2025.	Kevzara	*Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France*	EU/1/17/1196	22.12.2025.
19.12.2025.	Kisqali	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/17/1221	22.12.2025.
19.12.2025.	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	22.12.2025.
19.12.2025.	Mayzent	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/19/1414	26.12.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
19.12.2025.	Mirvaso	*Galderma International Tour Europlaza, 20 avenue André Prothin, La Défense 4, La Défense Cedex 92927, France*	EU/1/13/904	22.12.2025.
19.12.2025.	Mvasi	*Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland*	EU/1/17/1246	23.12.2025.
19.12.2025.	PHEBURANE	*Eurocept International BV Trapgans 5, 1244 RL Ankeveen, Nederland*	EU/1/13/822	23.12.2025.
19.12.2025.	Qdenga	*Takeda Pharmaceuticals International AG Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, Co. Dublin, D02 HW68, Ireland*	EU/1/22/1699	29.12.2025.
19.12.2025.	Seebri Breezhaler	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/12/788	22.12.2025.
19.12.2025.	Teriparatide SUN	*Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87, 2132JH Hoofddorp, Nederland*	EU/1/22/1697	5.1.2026.
19.12.2025.	Topotecan Hospira	*Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België*	EU/1/10/633	22.12.2025.
19.12.2025.	Voriconazole Hikma	*Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó n.º 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal*	EU/1/15/1004	22.12.2025.
19.12.2025.	Votrient	*Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland*	EU/1/10/628	22.12.2025.

— **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
4.12.2025.	Granupas	*Eurocept International B.V. Trapgans 5, 1244 RL Ankeveen, Nederland*	EU/1/13/896	10.12.2025.
5.12.2025.	Ronapreve	*Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland*	EU/1/21/1601	8.12.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
15.12.2025.	ABSIMKY	*Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España*	EU/1/24/1880	16.12.2025.
18.12.2025.	Lyxumia	*Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France*	EU/1/12/811	19.12.2025.
18.12.2025.	Mimpara	*Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland*	EU/1/04/292	7.1.2026.
19.12.2025.	Copiktra	*Secura Bio Limited 32 Molesworth Street, Dublin 2 D02 Y512, Co. Dublin, Ireland*	EU/1/21/1542	5.1.2026.

— **Tirdzniecības atļaujas atlikšana** (20. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004)

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
9.12.2025.	Oxbryta	*Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België*	EU/1/21/1622	10.12.2025.

— **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
4.12.2025.	Vaxxinact H5	Putnu gripas vakcīna (rekombinantā subvienību)	*Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland*	EU/2/25/356	Emulsija injekcijai	QI01AA23	8.12.2025.
18.12.2025.	ECOVAXXIN MS	Mycoplasma synoviae vakcīna (dzīva)	*Eco Animal Health Europe Ltd 6th Floor, South Bank House, Barrow Street, Dublin 4 D04 TR29, Ireland*	EU/2/25/357	Acu pilieni, suspensija	QI01AE03	22.12.2025.

— **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
18.12.2025.	AdTab	*Elanco GmbH* *Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland*	EU/2/22/288	22.12.2025.
18.12.2025.	Credelio Plus	*Elanco GmbH* *Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland*	EU/2/21/271	22.12.2025.
18.12.2025.	Enteroporc Coli AC	*Ceva Santé Animale* *10 avenue de La Ballastière, 33500 Libourne, France*	EU/2/20/262	19.12.2025.
18.12.2025.	FRONTPRO	*Boehringer Ingelheim Vetmedica GmbH* *D-55216 Ingelheim am Rhein, Deutschland*	EU/2/19/240	19.12.2025.
18.12.2025.	Kriptazen	*Virbac* *1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France*	EU/2/18/234	22.12.2025.
18.12.2025.	Librela	*Zoetis Belgium* *rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique*	EU/2/20/261	19.12.2025.
18.12.2025.	Lotimax	*Elanco GmbH* *Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland*	EU/2/24/311	22.12.2025.
18.12.2025.	Melosus	*CP-Pharma Handelsgesellschaft mbH* *Ostlandring 13, 31303 Burgdorf, Deutschland*	EU/2/10/116	22.12.2025.
18.12.2025.	YURVAC RHD	*Laboratorios Hipra, S.A.* *Avda. La Selva, 135, 17170 Amer (Girona), España*	EU/2/23/298	23.12.2025.
18.12.2025.	Zenalpha	*Vetcare Oy* *P.O. Box 99, 24101 Salo, Suomi*	EU/2/21/279	19.12.2025.
22.12.2025.	Credelio	*Elanco GmbH* *Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland*	EU/2/17/206	5.1.2026.
22.12.2025.	Vectormune FP ILT + AE	*Ceva-Phylaxia Co. Ltd.* *Szállás u. 5, 1107 Budapest, Magyarország*	EU/2/20/250	1.1.2026.

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