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Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2026. gada 1. februāris līdz 2026. gada 28. februāris

(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/2026/1816)

— **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
10.2.2026.	Gotenfia	golimumabs	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/2009	Koncentrāts injekciju šķīduma pagatavošanai	L04AB06	12.2.2026.
10.2.2026.	Ranluspec	ranibizumabum	Lupin Europe GmbH Hanauer Landstraße 139-143, 60314 Frankfurt, Deutschland	EU/1/25/2012	Šķīdums injekcijai Šķīdums injekcijām pilnšļircē	S01LA04	17.2.2026.
12.2.2026.	Aumseqa	aumolertinib	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/25/2006	Apvalkotās tabletes	L01EB11	13.2.2026.
12.2.2026.	EXDENSUR	Depemokimabs	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/25/2007	Šķīdums injekcijai	R03DX12	16.2.2026.
12.2.2026.	mNEXSPIKE	COVID-19 mRNS vakcīna	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/25/2010	Dispersija injekcijām	J07BN01	13.2.2026.

([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
12.2.2026.	MYQORZO	aficamten	Cytokinetics (Ireland) Limited 45 Mespil Rd. Dublin D04 W2F1 Ireland	EU/1/25/2014	Apvalkotās tabletes	Pending	13.2.2026.
16.2.2026.	ANKTIVA	nogapendekin alfa inbakicept	ImmunityBio Ireland Limited 6th Floor, 2 Grand Canal Square, Dublin 2, D02 A342, Ireland	EU/1/25/2002	Koncentrāts intravezikāli lietojamas suspensijas pagatavošanai.	L03AC03	17.2.2026.
20.2.2026.	Deltyba	Delamanid	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	Apvalkotās tabletes	J04AK06	23.2.2026.

— **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
4.2.2026.	Actelsar HCT	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/13/817	6.2.2026.
4.2.2026.	Lytenava	Outlook Therapeutics NL B.V. Strawinskylaan 569, 1077XX Amsterdam, Nederland	EU/1/24/1798	5.2.2026.
4.2.2026.	Nucala	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/15/1043	5.2.2026.
10.2.2026.	Carbaglu	Recordati Rare Diseases Tour Hekla, 52 Avenue Du General De Gaulle, 92800 Puteaux, France	EU/1/02/246	16.2.2026.
10.2.2026.	Casgevy	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/23/1787	12.2.2026.
10.2.2026.	Emadine	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/98/095	11.2.2026.
10.2.2026.	Enspryng	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1559	11.2.2026.
10.2.2026.	JEMPERLI	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/21/1538	13.2.2026.
10.2.2026.	Kengrexal	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/15/994	17.2.2026.
10.2.2026.	Myalepta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/18/1276	11.2.2026.
10.2.2026.	Relistor	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/08/463	13.2.2026.
10.2.2026.	Retsevmo	Eli Lilly Nederland B.V. Orteliuslaan 1000, 3528 BD, Nederland	EU/1/20/1527	11.2.2026.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
10.2.2026.	Uplizna	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1602	11.2.2026.
10.2.2026.	Vfend	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/212	11.2.2026.
12.2.2026.	Akynzeo	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	13.2.2026.
12.2.2026.	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/05/315	15.2.2026.
12.2.2026.	Bronchitol	Pharmaxis Europe Limited 108 Q House, Furze Road, Sandyford, Dublin 18, D18AY29, Ireland	EU/1/12/760	16.2.2026.
12.2.2026.	Emblaveo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1808	13.2.2026.
12.2.2026.	EndolucinBeta	ITM Medical Isotopes GmbH Lichtenbergstraße 1, 85748 Garching/München, Deutschland	EU/1/16/1105	13.2.2026.
12.2.2026.	Klisyri	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/21/1558	13.2.2026.
12.2.2026.	Mvabea	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1445	13.2.2026.
12.2.2026.	Orladeyo	Biocryst Ireland Limited Block 4, Harcourt Centre, Harcourt Road, Dublin 2, D02 HW77, Ireland	EU/1/21/1544	13.2.2026.
12.2.2026.	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	13.2.2026.
12.2.2026.	Ponvory	LABORATOIRES JUVISE PHARMACEUTICALS 149 Boulevard Bataille de Stalingrad, 69100 Villeurbanne, France	EU/1/21/1550	18.2.2026.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
12.2.2026.	Skyrizi	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1361	13.2.2026.
12.2.2026.	Veoza	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/23/1771	17.2.2026.
12.2.2026.	Yondelis	Pharma Mar S.A. Avenida de los Reyes 1, Polígono Industrial La Mina, 28770 Colmenar Viejo, Madrid, España	EU/1/07/417	18.2.2026.
12.2.2026.	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	13.2.2026.
16.2.2026.	Abraxane	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/428	17.2.2026.
16.2.2026.	SIMBRINZA	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/933	17.2.2026.
16.2.2026.	Strensiq	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1015	18.2.2026.
16.2.2026.	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	17.2.2026.
16.2.2026.	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	17.2.2026.
18.2.2026.	Busulfan Fresenius Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/14/951	19.2.2026.
18.2.2026.	Dimethyl fumarate Neuraxpharm	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1810	23.2.2026.
18.2.2026.	Irbesartan Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/06/376	23.2.2026.
18.2.2026.	Jylamvo	Oresund Pharma ApS Orient Plads 1, 2150 Nordhavn, Danmark	EU/1/17/1172	20.2.2026.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
18.2.2026.	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	19.2.2026.
18.2.2026.	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	19.2.2026.
18.2.2026.	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090	19.2.2026.
18.2.2026.	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	20.2.2026.
18.2.2026.	Pritor	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/089	19.2.2026.
18.2.2026.	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	19.2.2026.
20.2.2026.	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	23.2.2026.
23.2.2026.	Afinitor	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/538	24.2.2026.
23.2.2026.	Atazanavir Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/19/1353	25.2.2026.
23.2.2026.	Balversa	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1841	24.2.2026.
23.2.2026.	Copalia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/372	24.2.2026.
23.2.2026.	Dafiro	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/371	24.2.2026.
23.2.2026.	Evkeeza	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/21/1551	24.2.2026.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
23.2.2026.	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	24.2.2026.
23.2.2026.	Obgemsa	PIERRE FABRE MEDICAMENT Les Cauquillous, 81500 Lavaur, France	EU/1/24/1822	2.3.2026.
23.2.2026.	Ravicti	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/15/1062	2.3.2026.
23.2.2026.	Sitagliptin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1633	25.2.2026.
23.2.2026.	Tabrecta	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1650	24.2.2026.
23.2.2026.	TAKHZYRO	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/18/1340	24.2.2026.
23.2.2026.	Telmisartan Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/10/639	25.2.2026.
23.2.2026.	Trazimera	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1295	24.2.2026.
23.2.2026.	Vectibix	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/07/423	24.2.2026.
23.2.2026.	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	10.3.2026.
23.2.2026.	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/918	24.2.2026.
23.2.2026.	Wilzin	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/04/286	24.2.2026.
25.2.2026.	Bimzelx	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/21/1575	2.3.2026.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
25.2.2026.	Bortezomib Fresenius Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/19/1397	26.2.2026.
25.2.2026.	Exforge HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/569	26.2.2026.
25.2.2026.	Neoatricon	BrePco Biopharma Ltd. Suite One, The Avenue, Beacon Court, Sandyford, Dublin D18HX31, Ireland	EU/1/24/1804	27.2.2026.
25.2.2026.	Nexium Control	Haleon Ireland Dungarvan Limited Knockbrack,Dungarvan, Co. Waterford, Ireland	EU/1/13/860	3.3.2026.
25.2.2026.	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	26.2.2026.
25.2.2026.	Orgovyx	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1642	26.2.2026.
25.2.2026.	Oslif Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/586	26.2.2026.
25.2.2026.	Strimvelis	Fondazione Telethon ETS Via Varese 16/B, 00185 Roma, Italia	EU/1/16/1097	26.2.2026.
25.2.2026.	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	26.2.2026.
25.2.2026.	Ultibro Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/862	26.2.2026.
26.2.2026.	Copalia HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/575	27.2.2026.
26.2.2026.	Dafiro HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/574	27.2.2026.
26.2.2026.	Exforge	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/370	27.2.2026.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
26.2.2026.	Incellipan	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1807	2.3.2026.
26.2.2026.	Pepaxti	Oncopeptides AB (publ) Luntmakargatan 46, 111 37 Stockholm, Sverige	EU/1/22/1669	3.3.2026.
26.2.2026.	Thiotepa Riemser	Esteve Pharmaceuticals GmbH Hohenzollerndamm 150-151, 14199 Berlin, Deutschland	EU/1/21/1536	27.2.2026.

— **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
18.2.2026.	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	20.2.2026.
23.2.2026.	Atazanavir Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/19/1353	2.3.2026.
23.2.2026.	Fluad Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/20/1433	24.2.2026.
23.2.2026.	Flucelvax Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/18/1326	25.2.2026.
23.2.2026.	Zegalogue	Zealand Pharma A/S Sydmarken 11, 2860 Soeborg, Danmark	EU/1/24/1829	24.2.2026.

— **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
25.2.2026.	Lotilaner/Milbemycin Elanco	lotilaners / milbemicīna oksīma	Elanco GmbH Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Deutschland	EU/2/26/361	Košļājamas tabletes	QP54AB51	27.2.2026.

ELI: http://data.europa.eu/eli/C/2026/1816/oj

— **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
16.2.2026.	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	23.2.2026.

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

European Medicines Agency
Domenico Scarlattilaan 6
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NETHERLANDS