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

Povzetek sklepov Evropske unije o dovoljenjih za promet z zdravili od 1. februar 2026 do 28. februar 2026

(Objavljeno v skladu s členom 13 ali členom 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta ([1]) ali Člen 5 Uredbe (EU) 2019/6 Evropskega parlamenta in Sveta ([2]))

(C/2026/1816)

— **Izdaja dovoljenja za promet** (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
10.2.2026	Gotenfia	golimumab	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/2009	koncentrat za raztopino za injiciranje	L04AB06	12.2.2026
10.2.2026	Ranluspec	ranibizumab	Lupin Europe GmbH Hanauer Landstraße 139-143, 60314 Frankfurt, Deutschland	EU/1/25/2012	Raztopina za injiciranje v napolnjeni injekcijski brizgi Rztopina za injiciranje	S01LA04	17.2.2026
12.2.2026	Aumseqa	aumolertinib	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/25/2006	Filmsko obložene tablete	L01EB11	13.2.2026
12.2.2026	EXDENSUR	depemokimab	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/25/2007	Rztopina za injiciranje	R03DX12	16.2.2026
12.2.2026	mNEXSPIKE	mRNK cepivo proti COVID-19	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/25/2010	Disperzija za injiciranje	J07BN01	13.2.2026

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

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
12.2.2026	MYQORZO	afikamten	Cytokinetics (Ireland) Limited 45 Mespil Rd. Dublin D04 W2F1 Ireland	EU/1/25/2014	Filmsko obložene tablete	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	Koncentrat za intravezikalno suspenzijo.	L03AC03	17.2.2026
20.2.2026	Deltyba	delamanid	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	Filmsko obložene tablete	J04AK06	23.2.2026

— **Sprememba dovoljenja za promet** (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

— **Ukinitev dovoljenja za promet** (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta)

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
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

— **Izdaja dovoljenja za promet** (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta; Člen 5 Uredbe (EU) 2019/6 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
25.2.2026	Lotilaner/Milbemycin Elanco	lotilaner / milbemicinoksim	Elanco GmbH Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Deutschland	EU/2/26/361	Žvečljive tablete	QP54AB51	27.2.2026

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

— **Sprememba dovoljenja za promet** (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta; Člen 5 Uredbe (EU) 2019/6 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
16.2.2026	Miraţaz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	23.2.2026

Kdor želi dobiti vpogled v javno poročilo o oceni zadevnih zdravil ter o zadevnih sklepih o zdravilih, se lahko obrne na naslov:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS