Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. prosinca 2025. do 31. prosinca 2025.

(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ([1]) ili Članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća ([2]))

(C/2026/402)

— **Izdavanje odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
22.12.2025.	WAYRILZ	Rilzabrutinib	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/25/1974	Filmom obložena tableta	Pending	23.12.2025.

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

— **Izmjena odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.	Vorikonazol 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.

— **Povlačenje odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

— **Obustava odobrenja za stavljanje u promet** (članak 20 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

— **Izdavanje odobrenja za stavljanje u promet** (članak 38 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća; Članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
4.12.2025.	Vaxxinact H5	Vakcina protiv ptičje gripe (rekombinantni podjedinični)	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/25/356	Emulzija za injekciju	QI01AA23	8.12.2025.
18.12.2025.	ECOVAXXIN MS	Cjepivo protiv Mycoplasma synoviae (živo)	Eco Animal Health Europe Ltd 6th Floor, South Bank House, Barrow Street, Dublin 4 D04 TR29, Ireland	EU/2/25/357	Kapi za oko, suspenzija	QI01AE03	22.12.2025.

— **Izmjena odobrenja za stavljanje u promet** (članak 38 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća; Članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS