Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. travnja 2025. do 30. travnja 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/2025/2785)

— **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
4.4.2025	Datroway	Datopotamab derukstekan	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/25/1915	Prašak za koncentrat za otopinu za infuziju	L01FX35	8.4.2025
4.4.2025	PAVBLU	aflibercept	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, A96 F2A8, Ireland	EU/1/25/1909	Otopina za injekciju (injekcija) Otopina za injekciju u napunjenoj štrcaljki	S01LA05	7.4.2025
15.4.2025	LEQEMBI	Lekanemab	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/24/1891	Koncentrat za otopinu za infuziju	N06DX04	15.4.2025
23.4.2025	Filspari	sparsentan	Vifor France 100–101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France	EU/1/23/1788	Filmom obložena tableta	C09XX01	25.4.2025

([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.

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
23.4.2025	LYNOZYFIC	linvoseltamab	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/25/1917	Koncentrat za otopinu za infuziju	L01FX	25.4.2025
23.4.2025	Vyjuvek	Beremagen geperpavek	Krystal Biotech Netherlands B.V. Atrium Gebouw, Strawinskylaan 3051, 1077 ZX Amsterdam, Noord-Holland, Nederland	EU/1/25/1918	Suspenzija i gel za gel	D03AX16	24.4.2025
25.4.2025	Trabectedin Accord	trabektedin	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/24/1902	Prašak za koncentrat za otopinu za infuziju	L01CX01	29.4.2025

ELI: http://data.europa.eu/eli/C/2025/2785/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
3.4.2025	Ketoconazole Esteve	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/14/965	4.4.2025
4.4.2025	Briumvi	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/23/1730	8.4.2025
4.4.2025	Capecitabine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/762	7.4.2025
4.4.2025	Darzalex	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/16/1101	7.4.2025
4.4.2025	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	7.4.2025
4.4.2025	Ecansya	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	7.4.2025
4.4.2025	Fingolimod Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1450	7.4.2025
4.4.2025	Finlee	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1767	7.4.2025
4.4.2025	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/20/1468	7.4.2025
4.4.2025	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/12/782	7.4.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
4.4.2025	Ketoconazole Esteve	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/14/965	8.4.2025
4.4.2025	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	7.4.2025
4.4.2025	Lenvima	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/15/1002	7.4.2025
4.4.2025	Lysodren	Esteve Pharmaceuticals S.A. Torre Esteve Passeig Zona Franca 109, 4º 08038 Barcelona, España	EU/1/04/273	8.4.2025
4.4.2025	Ondexxya	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1345	7.4.2025
4.4.2025	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	7.4.2025
4.4.2025	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	8.4.2025
4.4.2025	Tafinlar	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/865	7.4.2025
4.4.2025	Waylivra	Akcea Therapeutics Ireland Ltd St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland	EU/1/19/1360	7.4.2025
4.4.2025	Xenleta	Venipharm 4 Bureaux De La Colline, 92210 Saint-Cloud, France	EU/1/20/1457	7.4.2025
4.4.2025	Zercepac	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1456	7.4.2025
10.4.2025	Columvi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	11.4.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.4.2025	Flucelvax	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1879	11.4.2025
14.4.2025	Arsenic trioxide Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1427	15.4.2025
14.4.2025	Livogiva	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/20/1462	15.4.2025
14.4.2025	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	15.4.2025
14.4.2025	Oyavas	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/20/1510	16.4.2025
14.4.2025	Xenleta	Venipharm 4 Bureaux De La Colline, 92210 Saint-Cloud, France	EU/1/20/1457	17.4.2025
16.4.2025	Ovaleap	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/13/871	22.4.2025
16.4.2025	Sprycel	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/06/363	22.4.2025
16.4.2025	Targretin	H.A.C. Pharma Pericentre 2, 43 Avenue De La Cote De Nacre, Caen, 14000, France	EU/1/01/178	22.4.2025
16.4.2025	Vafseo	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37, 58638 Iserlohn, Deutschland	EU/1/23/1725	23.4.2025
17.4.2025	Alymsys	Mabxience Research SL C/ Manuel Pombo Angulo 28, 28050 Madrid, España	EU/1/20/1509	22.4.2025
17.4.2025	Enbrel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/126	23.4.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
17.4.2025	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	24.4.2025
23.4.2025	Ahzantive	Formycon AG 82152 Martinsried/Planegg, Deutschland	EU/1/24/1888	24.4.2025
23.4.2025	Apixaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1458	24.4.2025
23.4.2025	AQUMELDI	Proveca Pharma Limited 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland	EU/1/23/1717	24.4.2025
23.4.2025	Insulin aspart Sanofi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1447	28.4.2025
23.4.2025	Lutathera	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/17/1226	28.4.2025
23.4.2025	Lyrica	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	25.4.2025
23.4.2025	MAVENCLAD	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/17/1212	24.4.2025
23.4.2025	Neparvis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/16/1103	28.4.2025
23.4.2025	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	24.4.2025
23.4.2025	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	25.4.2025
23.4.2025	Spikevax	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/20/1507	25.4.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.4.2025	TOBI Podhaler	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/10/652	25.4.2025
23.4.2025	Tremfya	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/17/1234	24.4.2025
23.4.2025	Upstaza	PTC Therapeutics International Limited 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/22/1653	28.4.2025
25.4.2025	Axumin	Blue Earth Diagnostics Ireland Ltd 6th Floor, 2 Grand Canal Square, Dublin 2, Ireland	EU/1/17/1186	29.4.2025
25.4.2025	Cufence	Univar Solutions B.V. Schouwburgplein 30, Rotterdam, 3012 CL, Nederland	EU/1/19/1365	30.4.2025
25.4.2025	Cuprior	Orphalan 226 Boulevard Voltaire, 75011 Paris, France	EU/1/17/1199	28.4.2025
25.4.2025	DaTSCAN	GE Healthcare B.V. De Rondom 8, 5612 AP, Eindhoven, Nederland	EU/1/00/135	28.4.2025
25.4.2025	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	30.4.2025
25.4.2025	Fabrazyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/01/188	29.4.2025
25.4.2025	IBRANCE	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1147	28.4.2025
25.4.2025	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1040	28.4.2025
25.4.2025	Koselugo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1552	28.4.2025
25.4.2025	Mixtard	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/02/231	29.4.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
25.4.2025	Orkambi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/15/1059	28.4.2025
25.4.2025	PREVYMIS	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/17/1245	29.4.2025
25.4.2025	Ryzneuta	Evive Biotechnology Ireland LTD 20 Kildare Street, Dublin 2, D02 T3V7, Ireland	EU/1/24/1793	2.5.2025
25.4.2025	SCENESSE	Clinuvel Europe Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/14/969	30.4.2025
25.4.2025	SOTYKTU	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1718	30.4.2025
25.4.2025	VANFLYTA	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/23/1768	29.4.2025

— **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
10.4.2025	Zostavax	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/06/341	11.4.2025
14.4.2025	Arsenic trioxide Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1427	15.4.2025
14.4.2025	Regkirona	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/21/1597	16.4.2025

— **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
2.4.2025	Omeprazole TriviumVet	omeprazola	TriviumVet DAC Unit 1N, Block 1A, Cleaboy Business Park, Old Kilmeaden Road, Waterford, X91 DEC4, Ireland	EU/2/25/336	Želučanootporna tvrda kapsula	QA02BC01	3.4.2025
23.4.2025	HEPIZOVAC	Cjepivo protiv epizootske hemoragijske bolesti (inaktiviran)	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/25/341	Suspenzija za injekciju	QI02AA	25.4.2025
23.4.2025	PRAZIVETIN	Prazikvantel	VETHELLAS S.A. 51, 31rst AUGOUSTOU STREET, 412 21 LARISSA, Ελλάδα	EU/2/25/340	Premiks za izradu ljekovite hrane za životinje	QP52AA01	28.4.2025
23.4.2025	Prevestrus vet	finrozol	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/25/338	Filmom obložena tableta	QG03XX90	25.4.2025
25.4.2025	Nobilis Multriva IBm+ND+EDS	Cjepivo protiv virusa zaraznog bronhitisa, Newcastleske bolesti i virusa sindroma pada nesivosti (inaktivirano)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/339	Emulzija za injekciju	QI01AA13	28.4.2025

— **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
2.4.2025	Cardalis	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/12/142	7.4.2025
2.4.2025	Clevor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/17/222	4.4.2025
2.4.2025	Coxatab	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/22/286	4.4.2025
2.4.2025	Hydrocortisone aceponate Ecuphar	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/18/230	7.4.2025
2.4.2025	Porcilis ColiClos	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/12/141	3.4.2025
2.4.2025	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	3.4.2025
2.4.2025	Simparica Trio	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/243	3.4.2025
10.4.2025	Innovax-ND-H5	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/315	11.4.2025
14.4.2025	Ingelvac CircoFLEX	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/07/079	16.4.2025
23.4.2025	Eluracat	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/23/297	25.4.2025
23.4.2025	Osurnia	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/14/170	29.4.2025
23.4.2025	Quadrisol	GROVET B.V. Centurionbaan 140, 3769 AV Soesterberg,Nederland	EU/2/97/005	28.4.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.4.2025	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	25.4.2025
23.4.2025	Suvaxyn PRRS MLV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	28.4.2025
23.4.2025	Veraflox	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/10/107	25.4.2025

— **Povlačenje 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)

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.4.2025	Pirsue	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/00/027	14.4.2025

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