Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. svibnja 2025. do 31. svibnja 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/2025/3366)

— **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
2.5.2025.	Deqsiga	imunoglobulin normalni, ljudski	Takeda Manufacturing Austria AG Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/25/1919	Otopina za infuziju	J06BA02	5.5.2025.
8.5.2025.	Columvi	глофитамаб	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	Koncentrat za otopinu za infuziju	L01FX28	12.5.2025.
8.5.2025.	Lorviqua	lorlatinib	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	Filmom obložena tableta	L01ED05	12.5.2025.
26.5.2025.	Jubereq	denosumab	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/25/1921	Otopina za injekciju	M05BX04	27.5.2025.
26.5.2025.	Osvyrti	denosumab	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/25/1922	Otopina za injekciju	M05BX04	27.5.2025.

([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.

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

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
2.5.2025.	Kizfizo	ORPHELIA Pharma 85 Boulevard Saint-Michel, 75005 Paris, France	-	5.5.2025.

— **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
2.5.2025.	Bylvay	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/21/1566	6.5.2025.
2.5.2025.	Calquence	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1479	5.5.2025.
2.5.2025.	Calquence	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1479	5.5.2025.
2.5.2025.	Clopidogrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	5.5.2025.
2.5.2025.	ELREXFIO	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1770	5.5.2025.
2.5.2025.	Entresto	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/15/1058	6.5.2025.
2.5.2025.	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1025	6.5.2025.
2.5.2025.	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	13.5.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
2.5.2025.	Ongentys	Bial - Portela & C[a], SA À Av. da Siderurgia Nacional, 4745-457 S. Mamede do Coronado, Portugal	EU/1/15/1066	5.5.2025.
2.5.2025.	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	5.5.2025.
2.5.2025.	Praluent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/15/1031	5.5.2025.
2.5.2025.	Spexotras	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1781	6.5.2025.
2.5.2025.	TachoSil	Corza Medical GmbH Speditionstraße 21, 40221 Düsseldorf, Deutschland	EU/1/04/277	6.5.2025.
2.5.2025.	Tevimbra	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	5.5.2025.
2.5.2025.	Tremfya	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/17/1234	5.5.2025.
2.5.2025.	Xydalba	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/14/986	5.5.2025.
8.5.2025.	Cystagon	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/97/039	12.5.2025.
8.5.2025.	Esbriet	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/11/667	12.5.2025.
8.5.2025.	Glyxambi	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/16/1146	15.5.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
8.5.2025.	Olumiant	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	12.5.2025.
8.5.2025.	Pirfenidone axunio	axunio Pharma GmbH Van-der-Smissen-Straße 1, 22767 Hamburg, Deutschland	EU/1/22/1655	14.5.2025.
8.5.2025.	Prevenar 13	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/09/590	12.5.2025.
8.5.2025.	RoActemra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/08/492	12.5.2025.
15.5.2025.	BEQVEZ	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1838	16.5.2025.
15.5.2025.	Korjuny	Atnahs Pharma Netherlands B. V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark	EU/1/24/1826	21.5.2025.
15.5.2025.	Mabthera	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/98/067	16.5.2025.
15.5.2025.	Onpattro	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/18/1320	20.5.2025.
15.5.2025.	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	20.5.2025.
15.5.2025.	Sorafenib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1696	19.5.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
15.5.2025.	Tysabri	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/06/346	16.5.2025.
15.5.2025.	Zilbrysq	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef 60, 1070 Brussel, België	EU/1/23/1764	20.5.2025.
16.5.2025.	IXCHIQ	Valneva Austria GmbH Campus Vienna Biocenter 3, 1030 Wien, Österreich	EU/1/24/1828	20.5.2025.
22.5.2025.	Breyanzi	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1631	23.5.2025.
22.5.2025.	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/20/1468	25.5.2025.
22.5.2025.	Kymriah	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1297	23.5.2025.
22.5.2025.	Lumeblue	Cosmo Technologies Ltd Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/20/1470	27.5.2025.
22.5.2025.	Mysimba	Orexigen Therapeutics Ireland Limited 9-10 Fenian Street, Dublin 2, D02 RX24, Ireland	EU/1/14/988	23.5.2025.
22.5.2025.	Qtern	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1108	23.5.2025.
22.5.2025.	Xromi	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/19/1366	26.5.2025.
26.5.2025.	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	28.5.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
26.5.2025.	Xofluza	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1500	27.5.2025.

— **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
2.5.2025.	Pemetreksed Baxter	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/22/1705	5.5.2025.
15.5.2025.	BEQVEZ	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1838	16.5.2025.

— **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
15.5.2025.	DIVENCE IBR Marker Live	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/318	19.5.2025.
15.5.2025.	Felpreva	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/21/277	16.5.2025.
22.5.2025.	Newflend ND H9	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/23/296	23.5.2025.
22.5.2025.	Zycortal	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/15/189	5.6.2025.

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
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NETHERLANDS