Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. lipnja 2026. do 30. lipnja 2026.

(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/2026/3946)

— **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. lipnja 2026.	Retsevmo	selperkatinib	Eli Lilly Nederland B.V. Orteliuslaan 1000, 3528 BD Utrecht, Nederland	EU/1/20/1527	Kapsula, tvrda	L01EX22	5.6.2026
19.6.2026	Cenrifki	tolebrutiniba	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/25/2011	Filmom obložena tableta	L04AA62	22.6.2026
19.6.2026	Palbociclib Viatris	palbociklib	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/26/2039	Filmom obložena tableta	L01EF01	22.6.2026
19.6.2026	Redemplo	plozasiran	Arrowhead Pharmaceuticals Ireland Limited One Spencer Dock, North Wall Quay, Dublin 1, D01 X9R7, Ireland	EU/1/26/2041	Otopina za injekciju	Pending	22.6.2026
19.6.2026	Rexatilux	Ranibizumab	Intas Third Party Sales 2005, S.L. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6a Planta, 08039, Barcelona, España	EU/1/26/2043	Otopina za injekciju Otopina za injekciju u napunjenoj štrcaljki	S01LA04	25.6.2026

([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
30.6.2026	Itvisma	onasemnogen abeparvovek	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/26/2038	Otopina za injekciju	M09AX09	1.7.2026

— **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
12.6.2026	Iloperidone Vanda Pharmaceuticals	Vanda Pharmaceuticals Netherlands B.V. Basisweg 10, 1043 AP Amsterdam, Nederland	-	18.6.2026

— **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
3.6.2026	Lojuxta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/13/851	5.6.2026
4.6.2026	Ahzantive	Formycon AG 82152 Martinsried/Planegg, Deutschland	EU/1/24/1888	8.6.2026
4.6.2026	Anzupgo	LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/24/1851	8.6.2026
4.6.2026	Cholestagel	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/03/268	9.6.2026
4.6.2026	Enbrel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/126	5.6.2026
4.6.2026	JEMPERLI	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/21/1538	9.6.2026
4.6.2026	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	5.6.2026
4.6.2026	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	5.6.2026
4.6.2026	Zejula	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/17/1235	9.6.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
8.6.2026	Aucatzyl	Autolus GmbH Im Schwarzenbach 4, 79576 Weil am Rhein, Deutschland	EU/1/25/1951	9.6.2026
8.6.2026	Pirfenidone Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/22/1707	9.6.2026
11.6.2026	Alkindi	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/17/1260	16.6.2026
11.6.2026	Aripiprazole Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1009	12.6.2026
11.6.2026	Doptelet	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/19/1373	18.6.2026
11.6.2026	Elaprase	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/06/365	15.6.2026
11.6.2026	Emtricitabine/ Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1133	12.6.2026
11.6.2026	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	30.6.2026
11.6.2026	Qoyvolma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/25/1925	13.6.2026
11.6.2026	Repaglinide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/743	12.6.2026
11.6.2026	Repaglinide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/530	12.6.2026
11.6.2026	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	12.6.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
11.6.2026	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	22.6.2026
11.6.2026	Voxzogo	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/21/1577	22.6.2026
12.6.2026	Alkindi	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/17/1260	16.6.2026
12.6.2026	Dazublys	CuraTeQ Biologics (Malta) Limited Vault 14 Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta	EU/1/25/1949	19.6.2026
12.6.2026	Dyrupeg	CuraTeQ Biologics (Malta) Limited Vault 14 Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta	EU/1/25/1914	19.6.2026
12.6.2026	Faslodex	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/03/269	15.6.2026
12.6.2026	Lorviqua	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	15.6.2026
12.6.2026	Rezzayo	Mundipharma GmbH De-Saint-Exupery-Strasse 10, 60549 Frankfurt Am Main, Deutschland	EU/1/23/1775	15.6.2026
12.6.2026	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	15.6.2026
12.6.2026	TALVEY	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1748	15.6.2026
12.6.2026	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	15.6.2026
12.6.2026	Xbryk	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1889	17.6.2026
12.6.2026	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	15.6.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.6.2026	Zefylti	CuraTeQ Biologics (Malta) Limited Vault 14 Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta	EU/1/24/1899	19.6.2026
19.6.2026	Alunbrig	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/18/1264	23.6.2026
19.6.2026	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	22.6.2026
19.6.2026	Columvi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	22.6.2026
19.6.2026	Constella	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/12/801	22.6.2026
19.6.2026	Fluenz	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1816	22.6.2026
19.6.2026	Gardasil 9	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1007	22.6.2026
19.6.2026	Gotenfia	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/2009	23.6.2026
19.6.2026	HETRONIFLY	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1870	22.6.2026
19.6.2026	Icandra	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/484	22.6.2026
19.6.2026	Inaqovi	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/23/1756	23.6.2026
19.6.2026	Kesimpta	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/21/1532	22.6.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.6.2026	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	22.6.2026
19.6.2026	Maviret	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/17/1213	22.6.2026
19.6.2026	Memantine Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/13/827	22.6.2026
19.6.2026	Mysimba	Orexigen Therapeutics Ireland Limited 9-10 Fenian Street, Dublin 2, D02 RX24, Ireland	EU/1/14/988	22.6.2026
19.6.2026	Ngenla	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1617	22.6.2026
19.6.2026	Ontozry	Angelini Pharma S.p.A Viale Amelia 70, 00181 Rome, Italia	EU/1/21/1530	22.6.2026
19.6.2026	Opzelura	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/23/1726	23.6.2026
19.6.2026	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	22.6.2026
19.6.2026	Palynziq	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/19/1362	29.6.2026
19.6.2026	Poteligeo	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/18/1335	23.6.2026
19.6.2026	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/22/1638	3.7.2026
19.6.2026	Rezdiffra	Madrigal Pharmaceuticals EU Limited 1 Castlewood Avenue, Dublin, D06 H685, Ireland	EU/1/25/1962	22.6.2026
19.6.2026	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	22.6.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.6.2026	Rizmoic	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/18/1291	2.7.2026
19.6.2026	Skyrizi	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1361	22.6.2026
19.6.2026	Spherox	CO.DON GmbH Deutscher Platz 5d, 04103 Leipzig, Deutschland	EU/1/17/1181	30.6.2026
19.6.2026	Vipdomet	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/13/843	23.6.2026
19.6.2026	Zessly	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1280	23.6.2026
19.6.2026	Zomarist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/483	22.6.2026
22.6.2026	Trodelvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/21/1592	23.6.2026
25.6.2026	ADVATE	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/03/271	26.6.2026
25.6.2026	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	26.6.2026
25.6.2026	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	26.6.2026
25.6.2026	Erbitux	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/04/281	26.6.2026
25.6.2026	Eucreas	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/425	26.6.2026
25.6.2026	Eydenzelt	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1895	30.6.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
25.6.2026	Lokelma	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1173	26.6.2026
25.6.2026	Olanzapine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/427	26.6.2026
25.6.2026	Rimmyrah	QILU PHARMA SPAIN S.L. Paseo de la Castellana 40, planta 8, 28046 Madrid, España	EU/1/23/1779	26.6.2026
25.6.2026	Sugammadex Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1583	26.6.2026
25.6.2026	Teysuno	Nordic Group B.V. Siriusdreef 41, 2132 WT Hoofddorp, Nederland	EU/1/11/669	29.6.2026
25.6.2026	Trimbow	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/17/1208	26.6.2026
25.6.2026	Truqap	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1820	26.6.2026
25.6.2026	Yescarta	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/18/1299	30.6.2026
25.6.2026	Zoledronic acid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/13/834	26.6.2026
26.6.2026	Levetiracetam Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/713	29.6.2026
26.6.2026	Revlimid	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/391	29.6.2026
26.6.2026	Tresiba	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/12/807	4.7.2026

— **Izmjena 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
19.6.2026	Hetlioz	Vanda Pharmaceuticals Netherlands B.V. Basisweg 10, 1043 AP Amsterdam, Nederland	EU/1/15/1008	23.6.2026

— **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
12.6.2026	Qoyvolma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/25/1925	16.6.2026

— **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
5.6.2026	CLYNAV	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/16/197	8.6.2026
5.6.2026	Solensia	Zoetis Belgium SA rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	10.6.2026

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