Službeni list Europske unije
HR Serija C
20.11.2026.
C/2026/6137

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. listopada 2026. do 31. listopada 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/2026/6137)

— **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
22.10.2026	Lynavoy	lineriksibat	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/26/2053	Filmom obložena tableta	A05AX08	30.10.2026

([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.

— **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
5.10.2026	Daxas	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/636	6.10.2026
5.10.2026	Dazparda	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/26/2029	7.10.2026
5.10.2026	ELAHERE	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/24/1866	6.10.2026
5.10.2026	Kostaive	Arcturus Therapeutics Europe B.V. Claude Debussylaan 10, 1082 MD Amsterdam, Nederland	EU/1/24/1873	12.10.2026
5.10.2026	Kovaltry	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/15/1076	7.10.2026
5.10.2026	Memantin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6ª planta, 08039 Barcelona, España	EU/1/13/880	6.10.2026
5.10.2026	Mirvaso	Galderma S.A.,the Netherlands Branch De Ruijterkade 6 1013 AA Amsterdam Nederland	EU/1/13/904	6.10.2026
5.10.2026	Tenofovir disoproxil Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1129	6.10.2026
5.10.2026	Vevzuo	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/25/1945	8.10.2026
5.10.2026	Yuvanci	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1859	7.10.2026
12.10.2026	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	13.10.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.10.2026	Vgenfli	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/25/1961	13.10.2026
15.10.2026	Apretude	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	19.10.2026
15.10.2026	Idefirix	SERB S.A. Avenue Louise 480, 1050 Bruxelles, Belgique / Louizalaan 480, 1050 Brussel, België	EU/1/20/1471	16.10.2026
15.10.2026	IMULDOSA	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6ª planta, 08039 Barcelona, España	EU/1/24/1872	19.10.2026
15.10.2026	JEVTANA	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/11/676	16.10.2026
15.10.2026	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	16.10.2026
15.10.2026	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	20.10.2026
16.10.2026	Anzupgo	LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/24/1851	20.10.2026
16.10.2026	AYVAKYT	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/20/1473	19.10.2026
16.10.2026	Celsentri	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/07/418	19.10.2026
16.10.2026	Cerezyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/97/053	20.10.2026
16.10.2026	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	19.10.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.10.2026	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	19.10.2026
16.10.2026	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	20.10.2026
16.10.2026	Qarziba	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1191	20.10.2026
16.10.2026	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	19.10.2026
16.10.2026	Trizivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/00/156	22.10.2026
16.10.2026	Tygacil	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/336	19.10.2026
16.10.2026	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	19.10.2026
16.10.2026	Vydura	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1645	19.10.2026
16.10.2026	WAYRILZ	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/25/1974	19.10.2026
16.10.2026	Zutectra	Biotest Pharma GmbH Landsteinerstraße 5, 63303 Dreieich, Deutschland	EU/1/09/600	20.10.2026
19.10.2026	Bemrist Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1441	20.10.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.10.2026	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	20.10.2026
19.10.2026	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	20.10.2026
19.10.2026	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	20.10.2026
22.10.2026	Abiraterone Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1571	23.10.2026
22.10.2026	Brukinsa	BeOne Medicines Netherlands B.V. Evert van de Beekstraat 1, 104, 1118 CL Schiphol, Nederland	EU/1/21/1576	23.10.2026
22.10.2026	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	26.10.2026
22.10.2026	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	23.10.2026
22.10.2026	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	27.10.2026
22.10.2026	YERVOY	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/698	23.10.2026
23.10.2026	Besremi	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/18/1352	27.10.2026
23.10.2026	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	26.10.2026

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.10.2026	Ervebo	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/19/1392	26.10.2026
23.10.2026	Juluca	ViiV Healthcare B.V. Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands	EU/1/18/1282	28.10.2026
23.10.2026	Pyzchiva	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	27.10.2026
23.10.2026	Taxotere	Boryung Europe Kft. Vaci Ut 33, 1134 Budapest XIII, Magyarország	EU/1/95/002	28.10.2026
23.10.2026	Vaborem	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/18/1334	28.10.2026
23.10.2026	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	26.10.2026

— **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
16.10.2026	GHRYVELIN	Atnahs Pharma Netherlands B.V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark	EU/1/18/1337	21.10.2026
22.10.2026	Comtess	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/98/082	27.10.2026
23.10.2026	Entacapone Orion	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/708	28.10.2026
23.10.2026	Trizivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/00/156	28.10.2026

— **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
23.10.2026	Cirbloc	Cjepivo za cirkovirus svinja (inaktivirano)	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/26/373	Emulzija za injekciju	QI09AA07	26.10.2026

— **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
12.10.2026	Felpreva	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/21/277	21.10.2026
15.10.2026	Firocoxib CP-Pharma	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/25/359	20.10.2026
15.10.2026	Leucofeligen FeLV/RCP	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/09/097	22.10.2026
23.10.2026	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	27.10.2026
23.10.2026	Easotic	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/08/085	27.10.2026
23.10.2026	GALLIPRANT	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/221	27.10.2026
23.10.2026	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/14/174	26.10.2026
23.10.2026	Rabitec	Ceva Santé Animale 8 rue de Logrono, 33500 Libourne, France	EU/2/17/219	28.10.2026
23.10.2026	Vectra 3D	Ceva Santé Animale 8 rue de Logrono, 33500 Libourne, France	EU/2/13/156	26.10.2026

— **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
23.10.2026	ERAVAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/16/199	30.10.2026

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
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1083 HS Amsterdam
NETHERLANDS