Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. studenoga 2025. do 30. studenoga 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/2025/6746)

— **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
17.11.2025	Acvybra	denosumab	Reddy Holding GmbH Kobelweg 95, Augsburg 86156, Deutschland	EU/1/25/1983	Otopina za injekciju	M05BX04	18.11.2025
17.11.2025	Degevma	denosumab	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/25/1985	Otopina za injekciju	M05BX04	18.11.2025
17.11.2025	Denosumab Intas	denosumab	Intas Third Party Sales 2005, S.L. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6a Planta, 08039, Barcelona, España	EU/1/25/1993	Otopina za injekciju	M05BX04	20.11.2025
17.11.2025	GOBIVAZ	golimumab	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Ireland	EU/1/25/1988	Otopina za injekciju	L04AB06	19.11.2025
17.11.2025	Kefdensis	denosumab	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1980	Otopina za injekciju u napunjenoj štrcaljki	M05BX04	18.11.2025

([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
17.11.2025	Lynkuet	elinzanetant	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/25/1991	Kapsula, meka	G02CX07	18.11.2025
17.11.2025	Ponlimsi	denosumab	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/25/1986	Otopina za injekciju	M05BX04	18.11.2025
17.11.2025	Usgena	ustekinumab	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1987	Otopina za injekciju	L04AC05	18.11.2025
17.11.2025	Xbonzy	denosumab	Reddy Holding GmbH Kobelweg 95, Augsburg 86156, Deutschland	EU/1/25/1982	Otopina za injekciju	M05BX04	19.11.2025
17.11.2025	Zvogra	denosumab	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1981	Otopina za injekciju	M05BX04	18.11.2025
18.11.2025	Brinsupri	brenzokatib	Insmed Netherlands B.V. Stadsplateau 7, 3521 AZ Utrecht, Nederland	EU/1/25/1995	Filmom obložena tableta	Pending	19.11.2025
21.11.2025	Rivaroxaban Koanaa	rivaroksabana	Koanaa Healthcare Spain, S.L. Carretera Nacional 340, number 122, 4° 4a, 08960 Sant Just Desvern (Barcelona), España	EU/1/25/1994	Raspadljivi film za usta	B01AF01	25.11.2025
24.11.2025	Kyinsu	ikodek inzulin / semaglutid	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/25/1992	Otopina za injekciju	A10AE57	27.11.2025
28.11.2025	Imaavy	nipokalimab	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/25/1989	Koncentrat za otopinu za infuziju	L04AL03	1.12.2025

ELI: http://data.europa.eu/eli/C/2025/6746/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
21.11.2025	Atropine sulfate FGK	FGK Representative Service GmbH Heimeranstraße 35, 80339 München, Deutschland	-	24.11.2025

— **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
3.11.2025	EU/3/23/2886	Kedrion S.p.A. Castelvecchio Pascoli, Localita Ai Conti Snc, 55051 Barga, LU, Italia	EU/3/23/2886	5.11.2025
3.11.2025	Lutathera	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/17/1226	4.11.2025
3.11.2025	Norvir	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/96/016	4.11.2025
3.11.2025	Polivy	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/19/1388	4.11.2025
3.11.2025	RAYVOW	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/21/1587	20.11.2025
6.11.2025	Bildyos	SciencePharma Sp. z o.o. Chełmska 30/34, 00-725 Warszawa, Polska	EU/1/25/1978	7.11.2025
6.11.2025	Bilprevda	SciencePharma Sp. z o.o. Chełmska 30/34, 00-725 Warszawa, Polska	EU/1/25/1979	7.11.2025
6.11.2025	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	7.11.2025
6.11.2025	Tryngolza	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/25/1969	7.11.2025
10.11.2025	AJOVY	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/19/1358	11.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.11.2025	Bydureon	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/696	11.11.2025
10.11.2025	Constella	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/12/801	12.11.2025
10.11.2025	Eribulin Baxter	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/24/1819	14.11.2025
10.11.2025	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	12.11.2025
10.11.2025	Hulio	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1319	12.11.2025
10.11.2025	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	11.11.2025
10.11.2025	Mepsevii	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/18/1301	11.11.2025
10.11.2025	Omlyclo	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1817	11.11.2025
10.11.2025	Pylclari	CURIUM PET France Biopole Clermont-Limagne, 3 rue Marie Curie, 63360 Saint-Beauzire, France	EU/1/23/1746	12.11.2025
10.11.2025	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/22/1638	17.11.2025
10.11.2025	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	11.11.2025
10.11.2025	Sapropterin Dipharma	Dipharma Arzneimittel GmbH Offheimer Weg 33, 65549 Limburg a. d. Lahn, Deutschland	EU/1/21/1620	12.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.11.2025	Tasigna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/422	11.11.2025
10.11.2025	Uplizna	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1602	11.11.2025
10.11.2025	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	11.11.2025
10.11.2025	Xultophy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/14/947	12.11.2025
10.11.2025	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	13.11.2025
17.11.2025	Apretude	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	19.11.2025
17.11.2025	Byfavo	PAION Pharma GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/20/1505	18.11.2025
17.11.2025	CANCIDAS	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/01/196	18.11.2025
17.11.2025	Celldemic	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1806	18.11.2025
17.11.2025	EU/3/24/2973	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/3/24/2973	18.11.2025
17.11.2025	Fintepla	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/20/1491	19.11.2025
17.11.2025	Heplisav B	Dynavax GmbH Eichsfelder Strasse 11, D-40595 Düsseldorf, Deutschland	EU/1/20/1503	24.11.2025
17.11.2025	Jaypirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1738	18.11.2025
17.11.2025	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	18.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
17.11.2025	Krazati	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1744	18.11.2025
17.11.2025	LIBTAYO	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/19/1376	18.11.2025
17.11.2025	Lumigan	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/02/205	18.11.2025
17.11.2025	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	18.11.2025
17.11.2025	Lupkynis	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	19.11.2025
17.11.2025	Lutetium (^{177}Lu) chloride Billev	Billev Pharma ApS Slotsmarken 10, 2970 Hørsholm, Danmark	EU/1/22/1680	24.11.2025
17.11.2025	Luxturna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1331	18.11.2025
17.11.2025	Ogivri	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1341	25.11.2025
17.11.2025	Ontozry	Angelini Pharma S.p.A Viale Amelia 70, 00181 Rome, Italia	EU/1/21/1530	18.11.2025
17.11.2025	Praxbind	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/15/1056	19.11.2025
17.11.2025	Remsima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/13/853	19.11.2025
17.11.2025	Scemblix	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1670	18.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
17.11.2025	Symkevi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/18/1306	18.11.2025
17.11.2025	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	19.11.2025
17.11.2025	Vabysmo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1683	18.11.2025
17.11.2025	Xofluza	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1500	18.11.2025
17.11.2025	Zejula	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/17/1235	18.11.2025
21.11.2025	Breyanzi	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1631	24.11.2025
21.11.2025	Cejemly	CStone Pharmaceuticals Ireland Limited 117-126 Sheriff Street Upper Dublin 1, D01 YC43, Ireland	EU/1/24/1833	24.11.2025
21.11.2025	Cetrotide	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/99/100	24.11.2025
21.11.2025	Coagadex	Kedrion S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca), Italia	EU/1/16/1087	24.11.2025
21.11.2025	CRYSVITA	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	17.12.2025
21.11.2025	Delstrigo	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1333	24.11.2025
21.11.2025	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	25.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
21.11.2025	Enzalutamide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/24/1842	24.11.2025
21.11.2025	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	24.11.2025
21.11.2025	Fymskina	Formycon AG Fraunhoferstraße 15, 82152 Martinsried/Planegg, Deutschland	EU/1/24/1862	25.11.2025
21.11.2025	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	24.11.2025
21.11.2025	Inbrija	Merz Therapeutics GmbH Eckenheimer Landstraße 100, 60318 Frankfurt Am Main, Deutschland	EU/1/19/1390	24.11.2025
21.11.2025	Libmeldy	Orchard Therapeutics (Netherlands) B.V. Bargelaan 200, 2333 CW Leiden, Nederland	EU/1/20/1493	24.11.2025
21.11.2025	Mevlyq	YES Pharmaceutical Development Services GmbH Basler Strasse 7, 61352 Bad Homburg, Deutschland	EU/1/23/1789	24.11.2025
21.11.2025	Nevanac	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/433	24.11.2025
21.11.2025	OXERVATE	Dompé farmaceutici S.p.A. Via San Martino 12, 20122 Milano, Italia.	EU/1/17/1197	26.11.2025
21.11.2025	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	24.11.2025
21.11.2025	Sogroya	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1501	24.11.2025
21.11.2025	Ulunar Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/917	24.11.2025
21.11.2025	Vizimpro	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1354	24.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
21.11.2025	Xoterna Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/863	24.11.2025
26.11.2025	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	28.11.2025
26.11.2025	Byetta	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/06/362	27.11.2025
26.11.2025	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	27.11.2025
26.11.2025	Erbitux	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/04/281	27.11.2025
26.11.2025	EU/3/07/471	Kedrion S.p.A. Castelvecchio Pascoli, Localita Ai Conti Snc, 55051 Barga, LU, Italia	EU/3/07/471	27.11.2025
26.11.2025	Eurartesim	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/11/716	28.11.2025
26.11.2025	Galafold	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/15/1082	27.11.2025
26.11.2025	Granupas	Eurocept International B.V. Trapgans 5, 1244 RL Ankeveen, Nederland	EU/1/13/896	27.11.2025
26.11.2025	Kineret	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/02/203	28.11.2025
26.11.2025	Lucentis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/374	27.11.2025
26.11.2025	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	28.11.2025
26.11.2025	Mepact	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/08/502	2.12.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
26.11.2025	Mycamine	Sandoz Pharmaceuticals d.d. Verovškova ulica 57, 1000 Ljubljana, Slovenija	EU/1/08/448	28.11.2025
26.11.2025	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	27.11.2025
26.11.2025	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	27.11.2025
26.11.2025	Remicade	Janssen-Cilag International N.V. Turnhoutseweg 30, 2340 Beerse, Antwerp, Belgie	EU/1/99/116	27.11.2025
26.11.2025	Sunitinib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1511	27.11.2025
26.11.2025	Teriflunomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1693	27.11.2025
26.11.2025	Travatan	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/199	27.11.2025
26.11.2025	Votubia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/710	27.11.2025

— **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
10.11.2025	Omidria	Rayner Surgical (Ireland) Limited The Mill Enterprise Hub, Newtown Link Road, Drogheda, A92 CD3D, Co. Louth, Ireland	EU/1/15/1018	11.11.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
17.11.2025	Bydureon	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/696	18.11.2025
21.11.2025	Telzir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/04/282	24.11.2025
26.11.2025	Byetta	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/06/362	27.11.2025

— **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
19.11.2025	Vaxxitek HVT+IBD +H5	cjepivo protiv ptičje gripe (živo rekombinantno)	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/25/354	Koncentrat i otapalo za suspenziju za injekciju.	QI01AD	19.11.2025
21.11.2025	Lenivia	izenivetmab	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/25/355	Otopina za injekciju (injekcija)	QN02BG93	26.11.2025

— **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
10.11.2025	Evanovo	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/22/284	11.11.2025
17.11.2025	VAXXON ND CLONE	IZO S.r.l. Via San Zeno 99/a 25124 Brescia (BS) Italia	EU/2/24/326	19.11.2025
21.11.2025	Emdocam	Emdoka John Lijsenstraat 16, 2321 Hoogstraten, België	EU/2/11/128	24.11.2025
26.11.2025	DIVENCE Tetra	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/310	27.11.2025
26.11.2025	Porcilis Porcoli Diluvac Forte	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/96/001	27.11.2025
26.11.2025	Recocam	Bimeda Animal Health Limited 2, 3 & 4 Airton Close,Tallaght, Dublin 24, Ireland	EU/2/11/133	27.11.2025

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