Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. lipnja 2025. do 30. lipnja 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/2025/4099)

— **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
2.6.2025	Qoyvolma	ustekinumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/25/1925	Koncentrat za otopinu za infuziju Otopina za injekciju	L04AC05	13.6.2025
2.6.2025	Ryjunea	atropinsulfat	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/25/1920	Kapi za oko, otopina	S01FA01	4.6.2025
6.6.2025	DUVYZAT	givinosztát	Italfarmaco S.p.A. Viale F. Testi, 330, 20126 Milano, Italia	EU/1/25/1930	Peroralna suspenzija	M09AX14	6.6.2025
11.6.2025	Xoanacyl	koordinacijski kompleks željezovog citrata	AVEROA SAS 11 Avenue Paul Verlaine, 38100 Grenoble, France	EU/1/25/1923	Filmom obložena tableta	V03AE08	12.6.2025
19.6.2025	Sephience	sepiapterin	PTC Therapeutics International Limited Unit 1, 52-55 Sir John Rogerson's Quay, Dublin 2, D02 NA07, Ireland	EU/1/25/1939	Oralni prašak bijele do bež boje u kapsulama za otvaranje ili vrećici.	A16AX28	25.6.2025

([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
19.6.2025	TEPEZZA	teprotumumab	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/25/1941	Prašak za koncentrat za otopinu za infuziju	L04AG13	22.6.2025
23.6.2025	Junod	denosumab	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/25/1933	Otopina za injekciju	M05BX04	2.7.2025
23.6.2025	Yaxwer	denosumab	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/25/1934	Otopina za injekciju	M05BX04	25.6.2025
25.6.2025	Vevzuo	denosumaba	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/25/1945	Otopina za injekciju	M05BX04	1.7.2025
26.6.2025	Denbrayce	denosumab	Mabxience Research SL C/ Manuel Pombo Angulo 28, 28050 Madrid, España	EU/1/25/1936	Otopina za injekciju	M05BX04	27.6.2025
26.6.2025	Enwylma	denosumab	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/25/1944	Otopina za injekciju	M05BX04	1.7.2025
26.6.2025	Izamby	denosumab	Mabxience Research SL C/ Manuel Pombo Angulo 28, 28050 Madrid, España	EU/1/25/1935	Otopina za injekciju	M05BX04	27.6.2025
26.6.2025	ZADENVI	denosumab	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/25/1937	Otopina za injekciju	M05BX04	1.7.2025
27.6.2025	Ziihera	zanidatamab	Jazz Pharmaceuticals Ireland Limited 5th Floor, Waterloo Exchange, Waterloo Road, Dublin 4, D04 E5W7, Ireland	EU/1/25/1931	Prašak za koncentrat za otopinu za infuziju	L01FD07	30.6.2025

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
30.6.2025	Alyftrek	deutivakaftora (deutivacaftor)/ tezakaftora (tezacaftor)/ vanzakaftora (vanzacaftor)	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/25/1943	Filmom obložena tableta	R07AX33	1.7.2025
30.6.2025	Dazublys	trastuzumab	CuraTeQ Biologics s.r.o Trtinova 260/1, Cakovice, 19600 Prague 9, Česká republika	EU/1/25/1949	Prašak za koncentrat za otopinu za infuziju	L01FD01	1.7.2025
30.6.2025	Evfraxy	denosumaba	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/25/1946	Otopina za injekciju	M05BX04	1.7.2025
30.6.2025	Oczyesa	oktreotid	Camurus AB Rydbergs Torg 4, 224 84 Lund, Sverige	EU/1/25/1938	Otopina za injekciju s produljenim oslobađanjem	H01CB02	1.7.2025

— **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
2.6.2025	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/12/794	3.6.2025
2.6.2025	ARIKAYCE liposomal	Insmed Netherlands B.V. Stadsplateau 7, 3521 AZ Utrecht, Nederland	EU/1/20/1469	3.6.2025
2.6.2025	Bosulif	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/818	3.6.2025
2.6.2025	Calquence	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1479	3.6.2025
2.6.2025	Evrysdi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1531	3.6.2025
2.6.2025	Fasturtec	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/00/170	3.6.2025
2.6.2025	Jivi	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/18/1324	3.6.2025
2.6.2025	Jyseleca	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/20/1480	3.6.2025
2.6.2025	Lytgobi	Taiho Pharma Netherlands B.V. Barbara Strozzilaan 201, 1083 HN Amsterdam, Noord-Holland, Nederland	EU/1/23/1741	3.6.2025
2.6.2025	Qdenga	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/22/1699	3.6.2025
2.6.2025	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	3.6.2025
2.6.2025	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	3.6.2025
2.6.2025	TALVEY	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1748	3.6.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
2.6.2025	Ultomiris	Alexion Europe SAS 103-105 Rue Anatole France, 92300 Levallois-Perret, France	EU/1/19/1371	3.6.2025
2.6.2025	VEGZELMA	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/22/1667	10.6.2025
2.6.2025	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/04/274	3.6.2025
2.6.2025	ZTALMY	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/23/1743	16.6.2025
4.6.2025	Tivdak	Genmab A/S Carl Jacobsens Vej 30, 2500 Valby, Danmark	EU/1/25/1911	5.6.2025
5.6.2025	Amvuttra	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/22/1681	6.6.2025
5.6.2025	Aybintio	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1454	9.6.2025
5.6.2025	Bemfola	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/13/909	12.6.2025
5.6.2025	Trodelvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/21/1592	6.6.2025
6.6.2025	Cabazitaxel Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1448	10.6.2025
6.6.2025	Cystadrops	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/15/1049	10.6.2025
6.6.2025	Fingolimod Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1573	10.6.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
6.6.2025	Flixabi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/16/1106	11.6.2025
6.6.2025	ORSERDU	Stemline Therapeutics B.V. Basisweg 10, 1043 AP, Amsterdam, Noord-Holland, Nederland	EU/1/23/1757	10.6.2025
6.6.2025	Pregabalin Viatris Pharma	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/14/916	18.6.2025
6.6.2025	Sugammadex Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1583	10.6.2025
6.6.2025	Sugammadex Piramal	Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland	EU/1/23/1739	15.5.2025
6.6.2025	Sugammadex Piramal	Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland	EU/1/23/1739	11.6.2025
6.6.2025	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	11.6.2025
6.6.2025	Velsipity	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1790	10.6.2025
12.6.2025	Atriance	Sandoz Pharmaceuticals d.d. Verovškova ulica 57, 1000 Ljubljana, Slovenija	EU/1/07/403	18.6.2025
12.6.2025	Elfabrio	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/23/1724	13.6.2025
12.6.2025	Emtricitabine /Tenofovir disoproxil Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1182	13.6.2025
12.6.2025	Inflectra	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/854	13.6.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.6.2025	Oncaspar	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes Cedex, France	EU/1/15/1070	13.6.2025
12.6.2025	Pregabalin Viatris Pharma	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/14/916	16.6.2025
12.6.2025	Xgeva	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/11/703	15.6.2025
12.6.2025	Zoonotic Influenza Vaccine Seqirus	Seqirus S.r.l. Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italia	EU/1/23/1761	13.6.2025
19.6.2025	Baraclude	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/06/343	20.6.2025
19.6.2025	BEYONTTRA	Bayer AG 51368 Leverkusen, Deutschland	EU/1/24/1906	25.6.2025
19.6.2025	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	20.6.2025
19.6.2025	Omidria	Rayner Surgical (Ireland) Limited The Mill Enterprise Hub, Newtown Link Road, Drogheda, A92 CD3D, Co. Louth, Ireland	EU/1/15/1018	7.7.2025
19.6.2025	Talzenna	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1377	20.6.2025
19.6.2025	Vyvgart	argenx BV Industriepark-Zwijnaarde 7, 9052 Gent, België	EU/1/22/1674	20.6.2025
23.6.2025	Adempas	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/907	24.6.2025
23.6.2025	AKEEGA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1722	25.6.2025
23.6.2025	Apremilast Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1796	25.6.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.6.2025	Cibinqo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	25.6.2025
23.6.2025	Fampridine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1477	25.6.2025
23.6.2025	Irbesartan / Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	26.6.2025
23.6.2025	Leflunomide Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/09/604	27.6.2025
23.6.2025	Pombiliti	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/22/1714	25.6.2025
23.6.2025	Poteligeo	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/18/1335	30.6.2025
23.6.2025	Respreeza	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/15/1006	26.7.2025
23.6.2025	Sogroya	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1501	25.6.2025
23.6.2025	Sugammadex Amomed	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/22/1708	3.6.2025
23.6.2025	Sugammadex Amomed	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/22/1708	25.6.2025
23.6.2025	Tepkinly	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	25.6.2025
23.6.2025	Vfend	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/212	25.6.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
25.6.2025	Amlodipin/Valsartan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1092	27.6.2025
25.6.2025	Avamys	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/07/434	30.6.2025
25.6.2025	Cufence	Univar Solutions B.V. Schouwburgplein 30, Rotterdam, 3012 CL, Nederland	EU/1/19/1365	1.7.2025
25.6.2025	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	26.6.2025
25.6.2025	HyQvia	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/13/840	27.6.2025
25.6.2025	Idefirix	Hansa Biopharma AB P.O. Box 785, 220 07 Lund, Sverige	EU/1/20/1471	27.6.2025
25.6.2025	Jivi	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/18/1324	26.6.2025
25.6.2025	ProQuad	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/323	27.6.2025
25.6.2025	Raxone	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/15/1020	26.6.2025
25.6.2025	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/15/992	26.6.2025
25.6.2025	Torisel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/424	26.6.2025
27.6.2025	Camcevi	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1647	30.6.2025
27.6.2025	Hycamtin	Sandoz Pharmaceuticals d.d. Verovškova ulica 57, 1000 Ljubljana, Slovenija	EU/1/96/027	30.6.2025

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
27.6.2025	Kapruvia	Vifor Fresenius Medical Care Renal Pharma France 100-101 terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/22/1643	30.6.2025
27.6.2025	Pedmarqsi	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/23/1734	1.7.2025

— **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
19.6.2025	BroPair Spiromax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/21/1534	25.6.2025
19.6.2025	Sixmo	L. Molteni & C. dei F.lli Alitti Società di .Esercizio .S.p.A Strada Statale 67, Loc. Granatieri, 50018 Scandicci (Firenze), Italia	EU/1/19/1369	30.6.2025

— **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
2.6.2025	Emevet	Maropitanta	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/25/343	Tablete za žvakanje	QA04AD90	4.6.2025
2.6.2025	Nobilis Multriva Gm+REOm	Cjepivo protiv virusa zarazne bolesti burze i ptičjeg reovirusa (inaktivirano)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/344	Emulzija za injekciju	QI01AA22	3.6.2025
2.6.2025	Nobilis Multriva IBm+ND	Cjepivo protiv virusa zaraznog bronhitisa ptica i virusa newcastleske bolesti (inaktivirano)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/342	Emulzija za injekciju	QI01AA10	3.6.2025
27.6.2025	Fluralaner Intervet	fluralaner	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/346	Tablete za žvakanje	QP53BE02	9.7.2025
27.6.2025	Nobilis Multriva IBm+ND+Gm +REOm+EDS	Cjepivo protiv zaraznog bronhitisa ptica, newcastleske bolesti, zarazne bolesti burze, ptičjeg reovirusa i virusa sindroma pada nesivosti (inaktivirano)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/345	Emulzija za injekciju	QI01AA25	1.7.2025

— **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
2.6.2025	Vectormune ND	CEVA-Phylaxia Co. Ltd Szállás u. 5, 1107 Budapest, Magyarország	EU/2/15/188	4.6.2025
27.6.2025	Coxatab	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/22/286	1.7.2025
27.6.2025	DIVENCE PENTA	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/307	2.7.2025
27.6.2025	HorStem	EquiCord S.L. 103-D Loeches, Polígono Industrial Ventorro del Cano, Alcorcón, 28925 Madrid, España	EU/2/18/226	2.7.2025
27.6.2025	Melovem	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonksveer, Nederland	EU/2/09/098	2.7.2025
27.6.2025	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	4.7.2025
27.6.2025	NexGard Combo	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/267	30.6.2025
27.6.2025	Oncept IL-2	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/13/150	30.6.2025
27.6.2025	Profender	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/05/054	30.6.2025
27.6.2025	Stronghold Plus	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	30.6.2025

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

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