ELI: http://data.europa.eu/eli/C/2024/5166/oj

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. srpnja 2024. do 31. srpnja 2024.

(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/2024/5166)

— **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
24.7.2024	Apexelsin	Paklitaksel	WhiteOak Pharmaceutical B.V. Teleportboulevard 130, Amsterdam, 1043 EJ, Nederland	EU/1/24/1835	Prašak za disperziju za infuziju	L01CD01	26.7.2024
24.7.2024	Cejemly	sugemalimab	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/24/1833	Koncentrat za otopinu za infuziju	L01FF11	25.7.2024
24.7.2024	DURVEQTIX	fidanakogen elaparvovek	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1838	Koncentrat za otopinu za infuziju	Pending	26.7.2024
24.7.2024	Kinpeygo	budezonid	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/22/1657	Kapsula s prilagođenim oslobađanjem, tvrda	A07EA06	29.7.2024
24.7.2024	Pomalidomide Krka	pomalidomid	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/24/1832	Kapsula, tvrda	L04AX06	25.7.2024
24.7.2024	Pomalidomide Zentiva	Pomalidomid	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/24/1830	Kapsula, tvrda	L04AX06	25.7.2024

([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
24.7.2024	Zegalogue	Dasiglukagona	Zealand Pharma A/S Sydmarken 11, 2860 Soeborg, Danmark	EU/1/24/1829	Otopina za injekciju	H04AA02	25.7.2024
26.7.2024	Avzivi	bevacizumab	FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland	EU/1/24/1834	Koncentrat za otopinu za infuziju	L01FG01	30.7.2024
26.7.2024	Dasatinib Accord Healthcare	dasatinib	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/24/1839	Filmom obložena tableta	L01EA02	29.7.2024
26.7.2024	Pomalidomide Accord	pomalidomid	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1831	Kapsula, tvrda	L04AX06	29.7.2024

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— **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
22.7.2024	Nezglyal	Minoryx Therapeutics S.L. Calle Ernest Lluch 32 Tcm 3, 08302 Mataro, España	-	23.7.2024

— **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
3.7.2024	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	4.7.2024
5.7.2024	Aldara	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/98/080	8.7.2024
5.7.2024	Carbaglu	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/02/246	10.7.2024
5.7.2024	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	8.7.2024
5.7.2024	Darunavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	8.7.2024
5.7.2024	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	8.7.2024
5.7.2024	Iressa	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/526	8.7.2024
5.7.2024	Jylamvo	Oresund Pharma ApS Orient Plads 1, 2150 Nordhavn, Hovedstaden, Danmark	EU/1/17/1172	8.7.2024
5.7.2024	Lonquex	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/13/856	8.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
5.7.2024	Neulasta	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227	8.7.2024
5.7.2024	NovoMix	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/00/142	8.7.2024
5.7.2024	Pergoveris	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/07/396	8.7.2024
5.7.2024	Ristaben	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/10/621	9.7.2024
5.7.2024	Ronapreve	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1601	8.7.2024
5.7.2024	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/15/992	8.7.2024
5.7.2024	Sibnayal	ADVICENNE 262, rue du Faubourg Saint Honoré 75008 Paris, France	EU/1/20/1517	8.7.2024
5.7.2024	Temozolomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/10/615	8.7.2024
5.7.2024	Tigecycline Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1394	8.7.2024
5.7.2024	TUKYSA	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/20/1526	11.7.2024
5.7.2024	ZTALMY	Marinus Pharmaceuticals Emerald Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1743	10.7.2024
8.7.2024	Sugammadex Amomed	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/22/1708	11.7.2024
8.7.2024	Tevimbra	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	9.7.2024
8.7.2024	Victoza	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/09/529	9.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.7.2024	Ocaliva	ADVANZ PHARMA Limited Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland	EU/1/16/1139	15.7.2024
12.7.2024	Ristfor	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/10/620	16.7.2024
12.7.2024	Soliris	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/07/393	15.7.2024
17.7.2024	Accofil	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/14/946	18.7.2024
17.7.2024	Fluenz	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1816	18.7.2024
17.7.2024	Galvus	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/414	18.7.2024
17.7.2024	GAVRETO	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/21/1555	18.7.2024
17.7.2024	Minjuvi	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1570	18.7.2024
17.7.2024	Rekovelle	Ferring Pharmaceuticals A/S Amager Strandvej 405, 2770 Kastrup, Danmark	EU/1/16/1150	23.7.2024
17.7.2024	Ritonavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1242	18.7.2024
17.7.2024	Tepkinly	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	18.7.2024
18.7.2024	Levetiracetam SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/741	25.7.2024
18.7.2024	Retacrit	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/431	18.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.7.2024	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	22.7.2024
19.7.2024	Piqray	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1455	22.7.2024
19.7.2024	Pregabalin Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/997	24.7.2024
19.7.2024	Scemblix	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1670	22.7.2024
19.7.2024	Votrient	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/628	22.7.2024
22.7.2024	Avonex	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/97/033	23.7.2024
22.7.2024	Byfavo	PAION Pharma GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/20/1505	25.7.2024
22.7.2024	Deferasirox Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1386	23.7.2024
22.7.2024	Norvir	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/96/016	23.7.2024
22.7.2024	Slenyto	RAD Neurim Pharmaceuticals EEC SARL 4 rue de Marivaux, 75002 Paris, France	EU/1/18/1318	25.7.2024
22.7.2024	Teriflunomide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/22/1698	23.7.2024
22.7.2024	VITRAKVI	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/19/1385	23.7.2024
23.7.2024	Prometax	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/98/092	25.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
24.7.2024	AUBAGIO	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/13/838	25.7.2024
24.7.2024	Buvidal	Camurus AB Ideon Science Park, 223 70 Lund, Sverige	EU/1/18/1336	25.7.2024
24.7.2024	Bydureon	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/696	25.7.2024
24.7.2024	Bylvay	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/21/1566	29.7.2024
24.7.2024	Caprelsa	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/11/749	25.7.2024
24.7.2024	Fluad Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/20/1433	25.7.2024
24.7.2024	Flucelvax Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/18/1326	25.7.2024
24.7.2024	Idefirix	Hansa Biopharma AB P.O. Box 785, 220 07 Lund, Sverige	EU/1/20/1471	25.7.2024
24.7.2024	Ilumetri	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/18/1323	29.7.2024
24.7.2024	JCOVDEN	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1525	25.7.2024
24.7.2024	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	25.7.2024
24.7.2024	Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/10/637	25.7.2024
24.7.2024	Leflunomide Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/09/604	29.7.2024
24.7.2024	Mvabea	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1445	25.7.2024
24.7.2024	Nexavar	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/06/342	25.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
24.7.2024	Pregabalin Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/997	25.7.2024
24.7.2024	Pyzchiva	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	30.7.2024
24.7.2024	Skyrizi	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1361	25.7.2024
24.7.2024	Suboxone	Indivior Europe Limited 27 Windsor Place, Dublin 2, D02 DK44, Ireland	EU/1/06/359	25.7.2024
24.7.2024	TUKYSA	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/20/1526	30.7.2024
26.7.2024	Artesunate Amivas	Amivas Ireland Ltd Suite 5, Second Floor, Station House, Railway Square, Waterford, Ireland	EU/1/21/1582	31.7.2024
26.7.2024	AYVAKYT	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/20/1473	29.7.2024
26.7.2024	Efficib	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/457	29.7.2024
26.7.2024	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	29.7.2024
26.7.2024	Epidyolex	Jazz Pharmaceuticals Ireland Ltd 5th Floor, Waterloo Exchange, Waterloo Road, Dublin D04 E5W7, Ireland	EU/1/19/1389	30.7.2024
26.7.2024	Fareston	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/96/004	29.7.2024
26.7.2024	Imcivree	Rhythm Pharmaceuticals Netherlands B.V. Radarweg 29, 1043 NX Amsterdam, Nederland	EU/1/21/1564	29.7.2024
26.7.2024	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	29.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
26.7.2024	Janumet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/455	29.7.2024
26.7.2024	Orladeyo	Biocryst Ireland Limited Block 4, Harcourt Centre, Harcourt Road, Dublin 2, D02 HW77, Ireland	EU/1/21/1544	29.7.2024
26.7.2024	Quinsair	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/973	31.7.2024
26.7.2024	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	29.7.2024
26.7.2024	Vabysmo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1683	29.7.2024
26.7.2024	Velmetia	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/456	29.7.2024
26.7.2024	Vumerity	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/21/1585	31.7.2024
26.7.2024	Zubsolv	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/17/1233	29.7.2024
29.7.2024	Atazanavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1091	30.7.2024
29.7.2024	Jalra	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/485	1.8.2024
29.7.2024	Lopinavir/Ritonavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1067	30.7.2024
29.7.2024	Myalepta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/18/1276	30.7.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
29.7.2024	Rasagiline Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1090	30.7.2024
29.7.2024	Xiliarx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/486	1.8.2024

— **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
5.7.2024	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, 1831 Diegem, België	EU/1/08/473	8.7.2024
5.7.2024	Tizveni	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/24/1797	10.7.2024
18.7.2024	Esmya	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/12/750	18.7.2024
26.7.2024	JCOVDEN	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1525	29.7.2024

— **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
5.7.2024	Nobilis Multriva RT +IBm+ND+Gm +REOm	Ptičji metapneumovirus, virus ptičjeg zaraznog bronhitisa, virus Newcastleske bolesti, virus ptičje zarazne bolesti burze i cjepivo protiv ptičjeg reovirusa (inaktivirano)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/317	Emulzija za injekciju	QI01AA26	8.7.2024
17.7.2024	Nobilis Multriva RT +IBm+ND+EDS	Cjepivo protiv ptičjeg metapneumovirusa, virusa infektivnog bronhitisa, virusa Newcastleske bolesti i sindroma pada nesivosti, inaktivirano.	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/316	Emulzija za injekciju	Pending	18.7.2024

— **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
5.7.2024	Felpreva	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/21/277	8.7.2024
5.7.2024	Forceris	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/19/235	8.7.2024
5.7.2024	Isemid	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/18/232	9.7.2024
5.7.2024	Nobivac LoVo L4	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/23/304	8.7.2024
5.7.2024	Vectra 3D	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/13/156	8.7.2024
5.7.2024	Vectra Felis	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/14/165	8.7.2024
5.7.2024	Virbagen Omega	VIRBAC 1ère Avenue - 2065m – L.I.D., 06516 CARROS, France	EU/2/01/030	8.7.2024
8.7.2024	Circovac	CEVA-Phylaxia Co. Ltd Szállás u. 5, 1107 Budapest, Magyarország	EU/2/07/075	10.7.2024
8.7.2024	HorStem	EquiCord S.L 103-D Loeches, Polígono. Industrial Ventorro del Cano, Alcorcón, 28925 Madrid, España.	EU/2/18/226	11.7.2024
11.7.2024	BLUEVAC BTV	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/11/122	12.7.2024
11.7.2024	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/026	12.7.2024

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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