Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. svibnja 2024. do 31. svibnja 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/2024/3877)

— **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
16.5.2024	Jubbonti	denosumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1813	Otopina za injekciju	M05BX04	21.5.2024
16.5.2024	Omlyclo	Omalizumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1817	Otopina za injekciju u napunjenoj štrcaljki	R03DX05	24.5.2024
17.5.2024	Awiqli	ikodek inzulin	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/24/1815	Otopina za injekciju u napunjenoj brizgalici	A10AE07	21.5.2024
17.5.2024	FABHALTA	iptakopan	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/24/1802	Kapsula, tvrda	L04AJ08	21.5.2024
17.5.2024	Wyost	denosumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1812	Otopina za injekciju	M05BX04	21.5.2024
27.5.2024	Lytenava	bevacizumab gama	Outlook Therapeutics Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/24/1798	Otopina za injekciju	S01LA08	28.5.2024

([1]) SL L 136, 30.4.2004, str. 1.
([2]) SL L 4, 7.1.2019, str. 43.

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
27.5.2024	Neoatricon	dopamin hidroklorid	BrePco Biopharma Ltd. Suite One, The Avenue, Beacon Court, Sandyford, Dublin D18HX31, Ireland	EU/1/24/1804	Otopina za infuziju	C01CA04	28.5.2024
29.5.2024	Agilus	dantrolène sodique hémiheptahydraté	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/24/1805	Prašak za otopinu za injekciju	M03CA01	30.5.2024
29.5.2024	Qalsody	tofersen	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/23/1783	Otopina za injekciju	N07XX22	3.6.2024

— **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
6.5.2024	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	7.5.2024
6.5.2024	Circadin	RAD Neurim Pharmaceuticals EEC SARL 4 rue de Marivaux, 75002 Paris, France	EU/1/07/392	7.5.2024
6.5.2024	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	8.5.2024
6.5.2024	Epclusa	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/16/1116	7.5.2024
6.5.2024	Fendrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/04/299	8.5.2024
6.5.2024	Kanuma	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1033	7.5.2024
6.5.2024	Kisplyx	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/16/1128	7.5.2024
6.5.2024	Orphacol	THERAVIA 16 Rue Montrosier, 92200 Neuilly-sur-Seine, France	EU/1/13/870	14.5.2024
6.5.2024	VEGZELMA	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/22/1667	7.5.2024
6.5.2024	Xenical	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/98/071	8.5.2024
10.5.2024	Armisarte	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/15/1063	13.5.2024
10.5.2024	Darunavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	13.5.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.5.2024	Fingolimod Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1450	13.5.2024
10.5.2024	Lojuxta	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/13/851	15.5.2024
10.5.2024	Nilemdo	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1425	13.5.2024
10.5.2024	Nustendi	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1424	14.5.2024
10.5.2024	PreHevbri	VBI Vaccines B.V. Delflandlaan 1, Queen's Tower Office Number 714, 1062 EA Amsterdam, Nederland	EU/1/22/1641	15.5.2024
10.5.2024	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/22/1638	14.5.2024
10.5.2024	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	13.5.2024
10.5.2024	Thalidomide Lipomed	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/22/1676	13.5.2024
10.5.2024	Thyrogen	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/99/122	14.5.2024
10.5.2024	Trevicta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/971	14.5.2024
10.5.2024	Tyverb	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/440	14.5.2024
15.5.2024	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	16.5.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.5.2024	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	17.5.2024
16.5.2024	Bondronat	Atnahs Pharma Netherlands B.V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark	EU/1/96/012	17.5.2024
16.5.2024	Cufence	Univar Solutions B.V. Schouwburgplein 30, Rotterdam, 3012 CL, Nederland	EU/1/19/1365	21.5.2024
16.5.2024	Giapreza	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/19/1384	17.5.2024
16.5.2024	IBRANCE	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1147	17.5.2024
16.5.2024	Imvanex	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/13/855	30.5.2024
16.5.2024	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	17.5.2024
16.5.2024	NUBEQA	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/20/1432	17.5.2024
16.5.2024	PecFent	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/10/644	22.5.2024
16.5.2024	Rinvoq	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	17.5.2024
16.5.2024	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	17.5.2024
16.5.2024	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	17.5.2024
16.5.2024	Saphnelo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1623	17.5.2024
16.5.2024	Vipidia	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/13/844	21.5.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.5.2024	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	20.5.2024
17.5.2024	Grasustek	Juta Pharma GmbH Gutenbergstr. 13, 24941, Flensburg, Deutschland	EU/1/19/1375	23.5.2024
17.5.2024	Levetiracetam Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/713	21.5.2024
17.5.2024	Methylthioninium chloride Proveblue	Provepharm S.A.S. 22 rue Marc Donadille, 13013 Marseille, France	EU/1/11/682	22.5.2024
17.5.2024	NUCEIVA	Evolus Pharma B.V. Apollolaan 151, 1077 AR Amsterdam, Nederland	EU/1/19/1364	21.5.2024
17.5.2024	Oxbryta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1622	21.5.2024
17.5.2024	Qdenga	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/22/1699	21.5.2024
17.5.2024	TRISENOX	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/02/204	22.5.2024
21.5.2024	Rivaroxaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1488	22.5.2024
22.5.2024	BEKEMV	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/23/1727	24.5.2024
22.5.2024	BiResp Spiromax	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/921	28.5.2024
22.5.2024	Bosulif	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/818	23.5.2024
22.5.2024	Buccolam	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/11/709	24.5.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.5.2024	DuoResp Spiromax	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/920	28.5.2024
22.5.2024	Ebilfumin	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/14/915	23.5.2024
22.5.2024	Eptifibatid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1065	23.5.2024
22.5.2024	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1025	23.5.2024
22.5.2024	Karvezide	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/085	24.5.2024
22.5.2024	Komboglyze	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/731	24.5.2024
22.5.2024	Lytgobi	Taiho Pharma Netherlands B.V. Barbara Strozzilaan 201, 1083 HN Amsterdam, Noord-Holland, Nederland	EU/1/23/1741	29.5.2024
22.5.2024	Menveo	GSK Vaccines S.r.l. Via Fiorentina 1, 53100 Siena, Italia	EU/1/10/614	27.5.2024
22.5.2024	Opzelura	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/23/1726	23.5.2024
22.5.2024	Procysbi	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/13/861	29.5.2024
22.5.2024	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/08/444	3.6.2024
22.5.2024	Sialanar	Proveca Pharma Limited 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland	EU/1/16/1135	23.5.2024
23.5.2024	Evrenzo	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1574	23.5.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.5.2024	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/11/702	28.5.2024
23.5.2024	Levetiracetam Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/701	23.5.2024
23.5.2024	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	23.5.2024
27.5.2024	Aimovig	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1293	28.5.2024
27.5.2024	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	28.5.2024
27.5.2024	Columvi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	28.5.2024
27.5.2024	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	28.5.2024
27.5.2024	IMJUDO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1713	28.5.2024
27.5.2024	Reyataz	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/03/267	28.5.2024
27.5.2024	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	28.5.2024
29.5.2024	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	26.4.2024
29.5.2024	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	30.5.2024
29.5.2024	Cerdelga	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/14/974	31.5.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
29.5.2024	Desloratadine Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/745	1.6.2024
29.5.2024	Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/17/1210	30.5.2024
29.5.2024	Emtricitabine/ Tenofovir disoproxil Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/16/1151	30.5.2024
29.5.2024	Emtricitabine /Tenofovir disoproxil Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1182	6.6.2024
29.5.2024	Myocet liposomal	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/00/141	3.6.2024
29.5.2024	Omidria	Rayner Surgical (Ireland) Limited The Mill Enterprise Hub, Newtown Link Road, Drogheda, A92 CD3D, Co. Louth, Ireland	EU/1/15/1018	4.6.2024
29.5.2024	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	6.6.2024

— **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
6.5.2024	Nobilis Multriva RT +IBm+ND+Gm +REOm+EDS	Cjepivo (inaktivirano) protiv ptičjeg metapneumovirusa, ptičjeg zaraznog bronhitisa, Newcastle bolesti, ptičje zarazne bolesti burze, ptičjeg reovirusa i virusa sindroma pada nesivosti.	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/309	Emulzija za injekciju	QI01AA24	8.5.2024
6.5.2024	Trilocur	trilostan	Emdoka John Lijsenstraat 16, 2321 Hoogstraten, België	EU/2/24/312	Peroralna suspenzija	QH02CA01	7.5.2024
6.5.2024	Trilorale	trilostan	Axience Tour Essor, 14 Rue Scandicci, 93500 Pantin, France	EU/2/24/313	Peroralna suspenzija	QH02CA01	7.5.2024
10.5.2024	DIVENCE Tetra	Cjepivo protiv virusa virusnog proljeva goveda tip 1 i tip 2 (podjedinica, rekombinantna), virusa parainfluence 3 goveda (inaktivirano) i goveđeg respiratornog sincicijskog virusa (živo)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/310	Liofilizat i otapalo za otopinu za injekciju	Pending	13.5.2024

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
22.5.2024	Innovax-ND-H5	Cjepivo protiv Newcastleske bolesti, ptičje gripe i Marekove bolesti (živo rekombinantno)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/315	Koncentrat i otapalo za suspenziju za injekciju.	QI01AD	23.5.2024
30.5.2024	RESPIVAC TRT	Virus purećeg rinotraheitisa, živi	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/314	Liofilizat za suspenziju	QI01AD01	3.6.2024

— **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
6.5.2024	Purevax RCP FeLV	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/048	8.5.2024
6.5.2024	RESPIPORC FLU-pan H1N1	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/209	13.5.2024
6.5.2024	Suiseng Diff/A	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	7.5.2024
6.5.2024	Zulvac BTV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/207	8.5.2024
10.5.2024	ProZinc	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/13/152	14.5.2024
30.5.2024	Advocate	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/03/039	3.6.2024
30.5.2024	Convenia	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/06/059	3.6.2024
30.5.2024	Cortavance	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/06/069	31.5.2024
30.5.2024	MS-H vaccine	Pharmsure Veterinary Products Europe Limited 4 Fitzwilliam Terrace, Strand Road, Bray, WICKLOW A98 T6H6, Ireland	EU/2/11/126	31.5.2024
30.5.2024	NEOLEISH	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/22/290	3.6.2024
30.5.2024	NexGard	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/13/159	31.5.2024
30.5.2024	Syvazul BTV	Laboratorios Syva S.A C/Marqués de la Ensenada16, 28004 Madrid, España	EU/2/18/231	3.6.2024
30.5.2024	UpCard	Vétoquinol SA Magny-Vernois, 70200 Lure, France	EU/2/15/184	4.6.2024

— **Obustava odobrenja za stavljanje u promet** (članak 45 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
15.5.2024	Kexxtone	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/12/145	17.5.2024

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

European Medicines Agency
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NETHERLANDS