Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. veljače 2025. do 28. veljače 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/2025/1825)

— **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
3.2.2025.	HETRONIFLY	serplulimab	Henlius Europe GmbH Sternstraße 67, 40479 Düsseldorf, Deutschland	EU/1/24/1870	Koncentrat za otopinu za infuziju	L01FF12	6.2.2025.
10.2.2025.	ANDEMBRY	garadacimab	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/24/1885	Otopina za injekciju	B06AC07	12.2.2025.
10.2.2025.	BEYONTTRA	akoramidis	BridgeBio Europe B.V. Weerdestein 97, 1083 GG Amsterdam, Noord-Holland, Nederland	EU/1/24/1906	Filmom obložena tableta	C01EB25	11.2.2025.
10.2.2025.	Korjuny	katumaksomab	Lindis Biotech GmbH Zeppelinstraße 4, 82178 Puchheim, Deutschland	EU/1/24/1826	Koncentrat za otopinu za infuziju	L01FX03	12.2.2025.
12.2.2025.	Emcitate	Tiratrikol	Rare Thyroid Therapeutics International AB Klara Norra Kyrkogata 26, 111 22 Stockholm, Sverige	EU/1/24/1897	Tableta za oralnu suspenziju	H03AA04	17.2.2025.
12.2.2025	Eydenzelt	aflibercepta	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1895	Otopina za injekciju	S01LA05	18.2.2025.

([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
12.2.2025.	Kostaive	zapomeran	Arcturus Therapeutics Europe B.V. Claude Debussylaan 10, 1082 MD Amsterdam, Nederland	EU/1/24/1873	Kostaive prašak za disperziju za injekciju	J07BX03	13.2.2025.
12.2.2025.	Nemluvio	nemolizumab	Galderma International La Defense 4, Tour Europlaza, 20 Avenue Andre Prothin, 92927 Paris La Defense Cedex, France	EU/1/24/1901	Prašak i otapalo za otopinu za injekciju	D11AH12	13.2.2025.
12.2.2025.	Obodence	denosumab	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1890	Otopina za injekciju u napunjenoj štrcaljki	M05BX04	13.2.2025.
12.2.2025.	WELIREG	belzutifan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/24/1893	Filmom obložena tableta	L01XX74	14.2.2025.
12.2.2025.	Xbryk	denosumab	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1889	Otopina za injekciju	M05BX04	13.2.2025.
12.2.2025.	Zefylti	Filgrastim	CuraTeQ Biologics s.r.o Trtinova 260/1, Cakovice, 19600 Prague 9, Česká republika	EU/1/24/1899	otopina za injekciju ili infuziju	L03AA02	14.2.2025.
14.2.2025.	Avtozma	tocilizumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1896	Koncentrat za otopinu za infuziju	L04AC07	24.2.2025.
14.2.2025.	Osenvelt	Denosumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1904	Otopina za injekciju	M05BX04	17.2.2025.

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
14.2.2025.	Stoboclo	Denosumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1905	Otopina za injekciju	M05BX04	21.2.2025.
14.2.2025.	Yesintek	Ustekinumab	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/24/1892	Koncentrat za otopinu za infuziju Otopina za injekciju	L04AC05	17.2.2025.
20.2.2025.	Seladelpar Gilead	seladelpar	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/24/1898	Kapsula, tvrda	A05AX07	21.2.2025.
26.2.2025.	Paxneury	gvanfacina	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1908	Tablete s produženim oslobađanjem	C02AC02	4.3.2025.
28.2.2025.	Tuzulby	metilfenidatklorida	Neuraxpharm Pharmaceuticals S.L. Avinguda De Barcelona 69, Poligono Industrialde La Fuensanta, 08970 Sant Joan Despi, España	EU/1/24/1907	Tableta za žvakanje s produljenim oslobađanjem.	N06BA04	3.3.2025.
28.2.2025.	VIMKUNYA	cjepivo protiv chikungunye (rekombinantno), adsorbirano	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/25/1916	Suspenzija za injekciju	Pending	28.2.2025.

— **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
3.2.2025.	Ambrisentan Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1368	5.2.2025.
3.2.2025.	Arsenic trioxide Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1427	5.2.2025.
3.2.2025.	Brintellix	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/13/891	4.2.2025.
3.2.2025.	Catiolanze	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/23/1763	5.2.2025.
3.2.2025	Ervebo	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/19/1392	4.2.2025.
3.2.2025.	Eucreas	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/425	4.2.2025.
3.2.2025.	EURneffy	ALK-Abelló A/S, Bøge Allé 6-8, 2970 Hørsholm, Danmark	EU/1/24/1846	7.2.2025.
3.2.2025.	Icandra	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/484	4.2.2025.
3.2.2025.	Kesimpta	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/21/1532	6.2.2025.
3.2.2025.	Kinzalkomb	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/02/214	4.2.2025.
3.2.2025.	MicardisPlus	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/02/213	5.2.2025.
3.2.2025.	Pregabalin Pfizer	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/14/916	4.2.2025.
3.2.2025.	Roclanda	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/20/1502	5.2.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
3.2.2025.	Ryeqo	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/21/1565	6.2.2025.
3.2.2025.	Zeffix	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/99/114	5.2.2025.
3.2.2025.	Zomarist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/483	4.2.2025.
7.2.2025.	Duloxetine Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1010	10.2.2025.
7.2.2025.	Piqray	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1455	10.2.2025.
7.2.2025.	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	5.3.2025.
7.2.2025.	Veoza	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/23/1771	13.2.2025.
10.2.2025.	Ambrisentan Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1368	12.2.2025.
10.2.2025.	GoResp Digihaler	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/19/1403	14.2.2025.
10.2.2025.	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	17.2.2025.
10.2.2025.	Ryzodeg	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/12/806	12.2.2025.
10.2.2025.	Semglee	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1270	11.2.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.2.2025.	Teysuno	Nordic Group B.V. Siriusdreef 41, 2132 WT Hoofddorp, Nederland	EU/1/11/669	13.2.2025.
10.2.2025.	Translarna	PTC Therapeutics International Limited Unit 1, 52-55 Sir John Rogerson's Quay, Dublin 2, D02 NA07, Ireland	EU/1/13/902	11.2.2025.
10.2.2025.	Tresiba	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/12/807	11.2.2025.
10.2.2025.	Xaluprine	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, Ireland	EU/1/11/727	11.2.2025.
12.2.2025.	Advagraf	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/07/387	13.2.2025.
12.2.2025.	Bemrist Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1441	17.2.2025.
12.2.2025.	Casgevy	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/23/1787	17.2.2025.
12.2.2025.	Envarsus	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/935	13.2.2025.
12.2.2025.	Filspari	Vifor France 100–101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France	EU/1/23/1788	13.2.2025.
12.2.2025.	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	13.2.2025.
12.2.2025.	Nepexto	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1436	14.2.2025.
12.2.2025.	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	14.2.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.2.2025.	Omvoh	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1736	13.2.2025.
12.2.2025.	Upstaza	PTC Therapeutics International Limited 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/22/1653	14.2.2025.
12.2.2025.	Zimbus Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1440	17.2.2025.
14.2.2025.	Arexvy	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/23/1740	18.2.2025.
14.2.2025.	Atectura Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1439	17.2.2025.
14.2.2025.	Avamys	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/07/434	20.2.2025.
14.2.2025.	Enerzair Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1438	17.2.2025.
14.2.2025.	IMJUDO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1713	17.2.2025.
14.2.2025.	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/09/523	17.2.2025.
14.2.2025.	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	27.2.2025.
14.2.2025.	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	18.2.2025.
14.2.2025.	Tepadina	ADIENNE S.r.l.S.U. Via Galileo Galilei 19, 20867 Caponago (MB), Italia	EU/1/10/622	17.2.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
14.2.2025.	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	17.2.2025.
14.2.2025.	Zoely	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/11/690	17.2.2025.
20.2.2025.	Bretaris Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/12/781	24.2.2025.
20.2.2025.	Brimica Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/14/963	24.2.2025
20.2.2025.	Cotellic	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/15/1048	24.2.2025.
20.2.2025.	Duaklir Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/14/964	24.2.2025.
20.2.2025.	Eklira Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/12/778	24.2.2025.
20.2.2025.	Hemlibra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/18/1271	21.2.2025.
20.2.2025.	Mekinist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/931	21.2.2025.
20.2.2025.	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	24.2.2025.
20.2.2025.	Sugammadex Piramal	Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland	EU/1/23/1739	24.2.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
20.2.2025	Uzpruvo	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/23/1784	24.2.2025.
20.2.2025.	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	24.2.2025.
21.2.2025.	Dynastat	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/209	24.2.2025.
21.2.2025.	Finlee	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1767	24.2.2025.
21.2.2025.	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	24.2.2025.
21.2.2025.	Zavesca	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/02/238	24.2.2025.
26.2.2025.	Aripiprazole Mylan Pharma	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1005	27.2.2025.
26.2.2025	Heplisav B	Dynavax GmbH Eichsfelder Strasse 11, D-40595 Düsseldorf, Deutschland	EU/1/20/1503	28.2.2025.
26.2.2025.	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	27.2.2025.
26.2.2025.	Lydisilka	Estetra SRL Rue Saint Georges 5-7, 4000 Liège, Belgique	EU/1/21/1548	27.2.2025.
26.2.2025.	Natpar	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1078	27.2.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
26.2.2025.	Peyona	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/09/528	28.2.2025.
26.2.2025.	Pregabalin Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1021	28.2.2025.
26.2.2025.	Prolia	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/10/618	2.3.2025.
26.2.2025.	Stayveer	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/832	27.2.2025.
26.2.2025.	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	27.2.2025.
26.2.2025.	Ucedane	Eurocept International B.V. Trapgans 5, 1244 RL Ankeveen, Nederland	EU/1/17/1202	5.3.2025.
26.2.2025.	Volibris	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/08/451	27.2.2025.
26.2.2025.	Voraxaze	SERB SAS 40 Avenue George V, 75008 Paris, France	EU/1/21/1586	28.2.2025.
28.2.2025.	Bevespi Aerosphere	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1339	3.3.2025.
28.2.2025.	Doptelet	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/19/1373	3.3.2025.
28.2.2025.	Drovelis	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/21/1547	5.3.2025.
28.2.2025.	Kymriah	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1297	4.3.2025.
28.2.2025.	Litfulo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1755	3.3.2025.
28.2.2025.	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	3.3.2025.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
28.2.2025.	Ronapreve	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1601	3.3.2025.
28.2.2025.	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	3.3.2025.
28.2.2025.	Truqap	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1820	3.3.2025.
28.2.2025.	YERVOY	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/698	3.3.2025.
28.2.2025.	Zelboraf	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/12/751	3.3.2025.

— **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
26.2.2025.	Mycapssa	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/22/1690	3.3.2025.

— **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
3.2.2025.	TOLFENAMIC ACID VMD	Tolfenamatna kiselina	V.M.D. Hoge Mauw 900, 2370 Arendonk, België	EU/2/24/329	Otopina za injekciju	QM01AG02	4.2.2025.
20.2.2025.	BLUEVAC-3	virus bolesti plavog jezika cjepivo (inaktiviran)	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/24/331	Suspenzija za injekciju	QI04AA02	21.2.2025.
20.2.2025.	Syvazul BTV 3	cjepivo protiv virusa plavog jezika (inaktivirano)	Laboratorios Syva S.A C/Marqués de la Ensenada16, 28004 Madrid, España	EU/2/24/332	Suspenzija za injekciju	QI04AA02	21.2.2025.
27.2.2025.	Nobilis Multriva REOm	Ptičji reovirus, soj ARV-1, inaktivirani, ptičji reovirus, soj ARV-4, inaktivirani	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/333	Emulzija za injekciju	QI01AA04	3.3.2025.

— **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
3.2.2025.	Profender	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/05/054	4.2.2025.
14.2.2025.	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	18.2.2025.
20.2.2025.	PREVEXXION RN	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/254	21.2.2025.
20.2.2025.	PREVEXXION RN +HVT	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/23/302	21.2.2025.
20.2.2025.	Vaxxitek HVT + IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/02/032	21.2.2025.
27.2.2025.	Newflend ND H9	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/23/296	3.3.2025.

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
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS