Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2025. gada 1. februāris līdz 2025. gada 28. februāris

(publicēts saskaņā ar 13. vai 38. pantu Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004 ([1]) vai Eiropas Parlamenta un Padomes Regulas (ES) 2019/6 5. pants ([2]))

(C/2025/1825)

— **Tirdzniecības atļaujas izsniegšana** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004): **Pieņemtas**

Lēmuma datums	Zāļu nosaukums	INN (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
3.2.2025.	HETRONIFLY	serplulimabs	*Henlius Europe GmbH Sternstraße 67, 40479 Düsseldorf, Deutschland*	EU/1/24/1870	Koncentrāts infūziju šķīduma pagatavošanai	L01FF12	6.2.2025.
10.2.2025.	ANDEMBRY	garadacimabs	*CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland*	EU/1/24/1885	Šķīdums injekcijai	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	Apvalkotās tabletes	C01EB25	11.2.2025.
10.2.2025.	Korjuny	katumaksomabs	*Lindis Biotech GmbH Zeppelinstraße 4, 82178 Puchheim, Deutschland*	EU/1/24/1826	Koncentrāts infūziju šķīduma pagatavošanai	L01FX03	12.2.2025.
12.2.2025.	Emcitate	Tiratrikols	*Rare Thyroid Therapeutics International AB Klara Norra Kyrkogata 26, 111 22 Stockholm, Sverige*	EU/1/24/1897	Disperģējamās tabletes	H03AA04	17.2.2025.
12.2.2025.	Eydenzelt	aflibercepta (afliberceptum)	*Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország*	EU/1/24/1895	Šķīdums injekcijai	S01LA05	18.2.2025.

([1]) OV L 136, 30.4.2004, 1. lpp., ELI: https://data.europa.eu/eli/reg/2004/726/oj.
([2]) OV L 4, 7.1.2019, 43. lpp., ELI: https://data.europa.eu/eli/reg/2019/6/oj.

Lēmuma datums	Zāļu nosaukums	INN (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
12.2.2025.	Kostaive	zapomerāns	*Arcturus Therapeutics Europe B.V. Claude Debussylaan 10, 1082 MD Amsterdam, Nederland*	EU/1/24/1873	Pulveris injekciju dispersijas pagatavošanai	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	Pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	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	Šķīdums injekcijām pilnšļircē	M05BX04	13.2.2025.
12.2.2025.	WELIREG	Belzutifāns (*belzutifanum*)	*Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland*	EU/1/24/1893	Apvalkotās tabletes	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	Šķīdums injekcijai	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	Šķīdums injekcijām vai infūzijām	L03AA02	14.2.2025.
14.2.2025.	Avtozma	tocilizumabs	*Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország*	EU/1/24/1896	Koncentrāts infūziju šķīduma pagatavošanai	L04AC07	24.2.2025.
14.2.2025.	Osenvelt	Denozumabs	*Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország*	EU/1/24/1904	Šķīdums injekcijai	M05BX04	17.2.2025.

Lēmuma datums	Zāļu nosaukums	INN (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
14.2.2025.	Stoboclo	Denozumabs	*Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország*	EU/1/24/1905	Šķīdums injekcijai	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	Koncentrāts infūziju šķīduma pagatavošanai Šķīdums injekcijai	L04AC05	17.2.2025.
20.2.2025.	Seladelpar Gilead	seladelpars	*Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland*	EU/1/24/1898	Cietās kapsulas	A05AX07	21.2.2025.
26.2.2025.	Paxneury	guanfacīna	*Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España*	EU/1/24/1908	Ilgstošas darbības tablete	C02AC02	4.3.2025.
28.2.2025.	Tuzulby	metilfenidāta hidrohlorīda	*Neuraxpharm Pharmaceuticals S.L. Avinguda De Barcelona 69, Poligono Industrialde La Fuensanta, 08970 Sant Joan Despi, España*	EU/1/24/1907	Ilgstošas darbības košļājamā tablete.	N06BA04	3.3.2025.
28.2.2025.	VIMKUNYA	Vakcīna pret čikungunjas vīrusu (rekombinanta, adsorbēta)	*Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark*	EU/1/25/1916	Suspensija injekcijai	Pending	28.2.2025.

— **Tirdzniecības atļaujas grozīšana** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004): **Pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, D15T867, 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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, D15T867, 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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, D15T867, Dublin 15, Ireland*	EU/1/15/1014	3.3.2025.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, D15T867, 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.

— **Tirdzniecības atļaujas izņemšana no aprites** (13. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004)

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
26.2.2025.	Mycapssa	*Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland*	EU/1/22/1690	3.3.2025.

— **Tirdzniecības atļaujas izsniegšana** (38. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004; Eiropas Parlamenta un Padomes Regulas (ES) 2019/6 5. pants): **Pieņemtas**

Lēmuma datums	Zāļu nosaukums	INN (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
3.2.2025.	TOLFENAMIC ACID VMD	Tolfenamīnskābe	*V.M.D.* *Hoge Mauw 900, 2370 Arendonk, België*	EU/2/24/329	Šķīdums injekcijai	QM01AG02	4.2.2025.
20.2.2025.	BLUEVAC-3	Vakcīna pret katarālā drudža vīrusu (inaktivēta)	*CZ Vaccines S.A.U.* *A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España*	EU/2/24/331	Suspensija injekcijai	QI04AA02	21.2.2025.
20.2.2025.	Syvazul BTV 3	infekciozā katarālā drudža vīrusa vakcīna (inaktivēta)	*Laboratorios Syva S.A* *C/Marqués de la Ensenada16, 28004 Madrid, España*	EU/2/24/332	Suspensija injekcijai	QI04AA02	21.2.2025.
27.2.2025.	Nobilis Multriva REOm	Putnu reovīruss, celms ARV-1, inaktivēts, putnu reovīruss, celms ARV-4, inaktivēts	*Intervet International B.V.* *Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland*	EU/2/24/333	Emulsija injekcijai	QI01AA04	3.3.2025.

— **Tirdzniecības atļaujas grozīšana** (38. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004; Eiropas Parlamenta un Padomes Regulas (ES) 2019/6 5. pants): **Pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Ikvienam, kurš vēlas apskatīt publisko novērtējuma ziņojumu par attiecīgajām zālēm un ar tām saistītos lēmumus, jāsazinās ar:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
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