ELI: http://data.europa.eu/eli/C/2025/1825/oj

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 February 2025 to 28 February 2025

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]) or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council ([2]))

(C/2025/1825)

— **Issuing of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
3.2.2025	HETRONIFLY	serplulimab	Henlius Europe GmbH Sternstraße 67, 40479 Düsseldorf, Deutschland	EU/1/24/1870	Concentrate for solution for infusion	L01FF12	6.2.2025
10.2.2025	ANDEMBRY	garadacimab	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/24/1885	Solution for injection	B06AC07	12.2.2025
10.2.2025	BEYONTTRA	acoramidis	BridgeBio Europe B.V. Weerdestein 97, 1083 GG Amsterdam, Noord-Holland, Nederland	EU/1/24/1906	Film-coated tablet	C01EB25	11.2.2025
10.2.2025	Korjuny	catumaxomab	Lindis Biotech GmbH Zeppelinstraße 4, 82178 Puchheim, Deutschland	EU/1/24/1826	Concentrate for solution for infusion	L01FX03	12.2.2025
12.2.2025	Emcitate	Tiratricol	Rare Thyroid Therapeutics International AB Klara Norra Kyrkogata 26, 111 22 Stockholm, Sverige	EU/1/24/1897	Dispersible tablet	H03AA04	17.2.2025
12.2.2025	Eydenzelt	Aflibercept	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1895	Solution for injection	S01LA05	18.2.2025

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

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
12.2.2025	Kostaive	zapomeran	Arcturus Therapeutics Europe B.V. Claude Debussylaan 10, 1082 MD Amsterdam, Nederland	EU/1/24/1873	Powder for dispersion for injection	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	Powder and solvent for solution for injection	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	Solution for injection in a pre-filled syringe	M05BX04	13.2.2025
12.2.2025	WELIREG	belzutifan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/24/1893	Film-coated tablet	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	Solution for injection	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	Solution for injection or infusion	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	Concentrate for solution for infusion	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	Solution for injection	M05BX04	17.2.2025

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
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	Solution for injection	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	Concentrate for solution for infusion Solution for injection	L04AC05	17.2.2025
20.2.2025	Seladelpar Gilead	seladelpar	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/24/1898	Capsule, hard	A05AX07	21.2.2025
26.2.2025	Paxneury	guanfacine	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1908	Prolonged-release tablet	C02AC02	4.3.2025
28.2.2025	Tuzulby	Methylphenidate hydrochloride	Neuraxpharm Pharmaceuticals S.L. Avinguda De Barcelona 69, Poligono Industrialde La Fuensanta, 08970 Sant Joan Despi, España	EU/1/24/1907	Prolonged-release chewable tablet	N06BA04	3.3.2025
28.2.2025	VIMKUNYA	Chikungunya vaccine (recombinant, adsorbed)	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/25/1916	Suspension for injection	Pending	28.2.2025

— **Modification of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

— **Withdrawal of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
26.2.2025	Mycapssa	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/22/1690	3.3.2025

— **Issuing of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
3.2.2025	TOLFENAMIC ACID VMD	Tolfenamic acid	V.M.D. Hoge Mauw 900, 2370 Arendonk, België	EU/2/24/329	Solution for injection	QM01AG02	4.2.2025
20.2.2025	BLUEVAC-3	Bluetongue virus vaccine (inactivated)	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/24/331	Suspension for injection	QI04AA02	21.2.2025
20.2.2025	Syvazul BTV 3	bluetongue virus vaccine (inactivated)	Laboratorios Syva S.A C/Marqués de la Ensenada16, 28004 Madrid, España	EU/2/24/332	Suspension for injection	QI04AA02	21.2.2025
27.2.2025	Nobilis Multriva REOm	Avian reovirus, strain ARV-1, Inactivated, Avian reovirus, strain ARV-4, Inactivated	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/333	Emulsion for injection	QI01AA04	3.3.2025

— **Modification of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
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

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS