ELI: http://data.europa.eu/eli/C/2025/6746/oj

Official Journal of the European Union

C/2025/6746

19.12.2025

EN
C series

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2025 to 30 November 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/2025/6746)

— **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
17.11.2025	Acvybra	Denosumab	Reddy Holding GmbH Kobelweg 95, Augsburg 86156, Deutschland	EU/1/25/1983	Solution for injection	M05BX04	18.11.2025
17.11.2025	Degevma	denosumab	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/25/1985	Solution for injection	M05BX04	18.11.2025
17.11.2025	Denosumab Intas	denosumab	Intas Third Party Sales 2005, S.L. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6a Planta, 08039, Barcelona, España	EU/1/25/1993	Solution for injection	M05BX04	20.11.2025
17.11.2025	GOBIVAZ	golimumab	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Ireland	EU/1/25/1988	Solution for injection	L04AB06	19.11.2025
17.11.2025	Kefdensis	denosumab	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1980	Solution for injection in a pre-filled syringe	M05BX04	18.11.2025

([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
17.11.2025	Lynkuet	elinzanetant	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/25/1991	Capsule, soft	G02CX07	18.11.2025
17.11.2025	Ponlimsi	denosumab	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/25/1986	Solution for injection	M05BX04	18.11.2025
17.11.2025	Usgena	ustekinumab	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1987	Solution for injection	L04AC05	18.11.2025
17.11.2025	Xbonzy	denosumab	Reddy Holding GmbH Kobelweg 95, Augsburg 86156, Deutschland	EU/1/25/1982	Solution for injection	M05BX04	19.11.2025
17.11.2025	Zvogra	denosumab	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1981	Solution for injection	M05BX04	18.11.2025
18.11.2025	Brinsupri	brensocatib	Insmed Netherlands B.V. Stadsplateau 7, 3521 AZ Utrecht, Nederland	EU/1/25/1995	Film-coated tablet	Pending	19.11.2025
21.11.2025	Rivaroxaban Koanaa	Rivaroxaban	Koanaa Healthcare Spain, S.L. Carretera Nacional 340, number 122, 4° 4a, 08960 Sant Just Desvern (Barcelona), España	EU/1/25/1994	Orodispersible film	B01AF01	25.11.2025
24.11.2025	Kyinsu	insulin icodec / semaglutide	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/25/1992	Solution for injection	A10AE57	27.11.2025
28.11.2025	Imaavy	nipocalimab	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/25/1989	Concentrate for solution for infusion	L04AL03	1.12.2025

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

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
21.11.2025	Atropine sulfate FGK	FGK Representative Service GmbH Heimeranstraße 35, 80339 München, Deutschland	-	24.11.2025

— **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
3.11.2025	EU/3/23/2886	Kedrion S.p.A. Castelvecchio Pascoli, Localita Ai Conti Snc, 55051 Barga, LU, Italia	EU/3/23/2886	5.11.2025
3.11.2025	Lutathera	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/17/1226	4.11.2025
3.11.2025	Norvir	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/96/016	4.11.2025
3.11.2025	Polivy	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/19/1388	4.11.2025
3.11.2025	RAYVOW	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/21/1587	20.11.2025
6.11.2025	Bildyos	SciencePharma Sp. z o.o. Chełmska 30/34, 00-725 Warszawa, Polska	EU/1/25/1978	7.11.2025
6.11.2025	Bilprevda	SciencePharma Sp. z o.o. Chełmska 30/34, 00-725 Warszawa, Polska	EU/1/25/1979	7.11.2025
6.11.2025	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	7.11.2025
6.11.2025	Tryngolza	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/25/1969	7.11.2025
10.11.2025	AJOVY	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/19/1358	11.11.2025

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
10.11.2025	Bydureon	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/696	11.11.2025
10.11.2025	Constella	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/12/801	12.11.2025
10.11.2025	Eribulin Baxter	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/24/1819	14.11.2025
10.11.2025	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	12.11.2025
10.11.2025	Hulio	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1319	12.11.2025
10.11.2025	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	11.11.2025
10.11.2025	Mepsevii	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/18/1301	11.11.2025
10.11.2025	Omlyclo	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1817	11.11.2025
10.11.2025	Pylclari	CURIUM PET France Biopole Clermont-Limagne, 3 rue Marie Curie, 63360 Saint-Beauzire, France	EU/1/23/1746	12.11.2025
10.11.2025	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/22/1638	17.11.2025
10.11.2025	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	11.11.2025
10.11.2025	Sapropterin Dipharma	Dipharma Arzneimittel GmbH Offheimer Weg 33, 65549 Limburg a. d. Lahn, Deutschland	EU/1/21/1620	12.11.2025

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
10.11.2025	Tasigna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/422	11.11.2025
10.11.2025	Uplizna	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1602	11.11.2025
10.11.2025	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	11.11.2025
10.11.2025	Xultophy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/14/947	12.11.2025
10.11.2025	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	13.11.2025
17.11.2025	Apretude	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	19.11.2025
17.11.2025	Byfavo	PAION Pharma GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/20/1505	18.11.2025
17.11.2025	CANCIDAS	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/01/196	18.11.2025
17.11.2025	Celldemic	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1806	18.11.2025
17.11.2025	EU/3/24/2973	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/3/24/2973	18.11.2025
17.11.2025	Fintepla	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/20/1491	19.11.2025
17.11.2025	Heplisav B	Dynavax GmbH Eichsfelder Strasse 11, D-40595 Düsseldorf, Deutschland	EU/1/20/1503	24.11.2025
17.11.2025	Jaypirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1738	18.11.2025
17.11.2025	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	18.11.2025

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
17.11.2025	Krazati	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1744	18.11.2025
17.11.2025	LIBTAYO	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/19/1376	18.11.2025
17.11.2025	Lumigan	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/02/205	18.11.2025
17.11.2025	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	18.11.2025
17.11.2025	Lupkynis	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	19.11.2025
17.11.2025	Lutetium (^{177}Lu) chloride Billev	Billev Pharma ApS Slotsmarken 10, 2970 Hørsholm, Danmark	EU/1/22/1680	24.11.2025
17.11.2025	Luxturna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1331	18.11.2025
17.11.2025	Ogivri	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1341	25.11.2025
17.11.2025	Ontozry	Angelini Pharma S.p.A Viale Amelia 70, 00181 Rome, Italia	EU/1/21/1530	18.11.2025
17.11.2025	Praxbind	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/15/1056	19.11.2025
17.11.2025	Remsima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/13/853	19.11.2025
17.11.2025	Scemblix	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1670	18.11.2025

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
17.11.2025	Symkevi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/18/1306	18.11.2025
17.11.2025	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	19.11.2025
17.11.2025	Vabysmo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1683	18.11.2025
17.11.2025	Xofluza	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1500	18.11.2025
17.11.2025	Zejula	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/17/1235	18.11.2025
21.11.2025	Breyanzi	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1631	24.11.2025
21.11.2025	Cejemly	CStone Pharmaceuticals Ireland Limited 117-126 Sheriff Street Upper Dublin 1, D01 YC43, Ireland	EU/1/24/1833	24.11.2025
21.11.2025	Cetrotide	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/99/100	24.11.2025
21.11.2025	Coagadex	Kedrion S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca), Italia	EU/1/16/1087	24.11.2025
21.11.2025	CRYSVITA	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	17.12.2025
21.11.2025	Delstrigo	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1333	24.11.2025
21.11.2025	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	25.11.2025

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
21.11.2025	Enzalutamide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/24/1842	24.11.2025
21.11.2025	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	24.11.2025
21.11.2025	Fymskina	Formycon AG Fraunhoferstraße 15, 82152 Martinsried/Planegg, Deutschland	EU/1/24/1862	25.11.2025
21.11.2025	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	24.11.2025
21.11.2025	Inbrija	Merz Therapeutics GmbH Eckenheimer Landstraße 100, 60318 Frankfurt Am Main, Deutschland	EU/1/19/1390	24.11.2025
21.11.2025	Libmeldy	Orchard Therapeutics (Netherlands) B.V. Bargelaan 200, 2333 CW Leiden, Nederland	EU/1/20/1493	24.11.2025
21.11.2025	Mevlyq	YES Pharmaceutical Development Services GmbH Basler Strasse 7, 61352 Bad Homburg, Deutschland	EU/1/23/1789	24.11.2025
21.11.2025	Nevanac	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/433	24.11.2025
21.11.2025	OXERVATE	Dompé farmaceutici S.p.A. Via San Martino 12, 20122 Milano, Italia.	EU/1/17/1197	26.11.2025
21.11.2025	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	24.11.2025
21.11.2025	Sogroya	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1501	24.11.2025
21.11.2025	Ulunar Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/917	24.11.2025
21.11.2025	Vizimpro	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1354	24.11.2025

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
21.11.2025	Xoterna Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/863	24.11.2025
26.11.2025	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	28.11.2025
26.11.2025	Byetta	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/06/362	27.11.2025
26.11.2025	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	27.11.2025
26.11.2025	Erbitux	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/04/281	27.11.2025
26.11.2025	EU/3/07/471	Kedrion S.p.A. Castelvecchio Pascoli, Localita Ai Conti Snc, 55051 Barga, LU, Italia	EU/3/07/471	27.11.2025
26.11.2025	Eurartesim	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/11/716	28.11.2025
26.11.2025	Galafold	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/15/1082	27.11.2025
26.11.2025	Granupas	Eurocept International B.V. Trapgans 5, 1244 RL Ankeveen, Nederland	EU/1/13/896	27.11.2025
26.11.2025	Kineret	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/02/203	28.11.2025
26.11.2025	Lucentis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/374	27.11.2025
26.11.2025	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	28.11.2025
26.11.2025	Mepact	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/08/502	2.12.2025

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
26.11.2025	Mycamine	Sandoz Pharmaceuticals d.d. Verovškova ulica 57, 1000 Ljubljana, Slovenija	EU/1/08/448	28.11.2025
26.11.2025	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	27.11.2025
26.11.2025	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	27.11.2025
26.11.2025	Remicade	Janssen-Cilag International N.V. Turnhoutseweg 30, 2340 Beerse, Antwerp, Belgie	EU/1/99/116	27.11.2025
26.11.2025	Sunitinib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1511	27.11.2025
26.11.2025	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	27.11.2025
26.11.2025	Travatan	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/199	27.11.2025
26.11.2025	Votubia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/710	27.11.2025

— **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
10.11.2025	Omidria	Rayner Surgical (Ireland) Limited The Mill Enterprise Hub, Newtown Link Road, Drogheda, A92 CD3D, Co. Louth, Ireland	EU/1/15/1018	11.11.2025

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
17.11.2025	Bydureon	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/696	18.11.2025
21.11.2025	Telzir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/04/282	24.11.2025
26.11.2025	Byetta	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/06/362	27.11.2025

— **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
19.11.2025	Vaxxitek HVT+IBD +H5	avian influenza vaccine (live recombinant)	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/25/354	Concentrate and solvent for suspension for injection	QI01AD	19.11.2025
21.11.2025	Lenivia	izenivetmab	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/25/355	Solution for injection in a vial	QN02BG93	26.11.2025

— **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
10.11.2025	Evanovo	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/22/284	11.11.2025
17.11.2025	VAXXON ND CLONE	IZO S.r.l. Via San Zeno 99/a 25124 Brescia (BS) Italia	EU/2/24/326	19.11.2025
21.11.2025	Emdocam	Emdoka John Lijsenstraat 16, 2321 Hoogstraten, België	EU/2/11/128	24.11.2025
26.11.2025	DIVENCE Tetra	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/310	27.11.2025
26.11.2025	Porcilis Porcoli Diluvac Forte	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/96/001	27.11.2025
26.11.2025	Recocam	Bimeda Animal Health Limited 2, 3 & 4 Airton Close,Tallaght, Dublin 24, Ireland	EU/2/11/133	27.11.2025

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