

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 April 2025 to 30 April 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/2025/2785)

— 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
4.4.2025	Datroway	Datopotamab deruxtecan	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/25/1915	Powder for concentrate for solution for infusion	L01FX35	8.4.2025
4.4.2025	PAVBLU	Aflibercept	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, A96 F2A8, Ireland	EU/1/25/1909	Solution for injection in a pre-filled syringe Solution for injection in a vial	S01LA05	7.4.2025
15.4.2025	LEQEMBI	Lecanemab	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/24/1891	Concentrate for solution for infusion	N06DX04	15.4.2025
23.4.2025	Filspari	Sparsentan	Vifor France 100–101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France	EU/1/23/1788	Film-coated tablet	C09XX01	25.4.2025

⁽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
23.4.2025	LYNOZYFIC	linvoseltamab	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/25/1917	Concentrate for solution for infusion	L01FX	25.4.2025
23.4.2025	Vyjuvek	Beremagene geperpavec	Krystal Biotech Netherlands B.V. Atrium Gebouw, Strawinskylaan 3051, 1077 ZX Amsterdam, Noord-Holland, Nederland	EU/1/25/1918	Suspension and gel for gel	D03AX16	24.4.2025
25.4.2025	Trabectedin Accord	trabectedin	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/24/1902	Powder for concentrate for solution for infusion	L01CX01	29.4.2025

— **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
3.4.2025	Ketoconazole Esteve	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/14/965	4.4.2025
4.4.2025	Briumvi	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/23/1730	8.4.2025
4.4.2025	Capecitabine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/762	7.4.2025
4.4.2025	Darzalex	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/16/1101	7.4.2025
4.4.2025	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	7.4.2025
4.4.2025	Ecansya	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	7.4.2025
4.4.2025	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	7.4.2025
4.4.2025	Finlee	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1767	7.4.2025
4.4.2025	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/20/1468	7.4.2025
4.4.2025	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/12/782	7.4.2025

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4.4.2025	Ketoconazole Esteve	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/14/965	8.4.2025
4.4.2025	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	7.4.2025
4.4.2025	Lenvima	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/15/1002	7.4.2025
4.4.2025	Lysodren	Esteve Pharmaceuticals S.A. Torre Esteve Passeig Zona Franca 109, 4º 08038 Barcelona, España	EU/1/04/273	8.4.2025
4.4.2025	Ondexxya	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1345	7.4.2025
4.4.2025	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	7.4.2025
4.4.2025	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	8.4.2025
4.4.2025	Tafinlar	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/865	7.4.2025
4.4.2025	Waylivra	Akcea Therapeutics Ireland Ltd St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland	EU/1/19/1360	7.4.2025
4.4.2025	Xenleta	Venipharm 4 Bureaux De La Colline, 92210 Saint-Cloud, France	EU/1/20/1457	7.4.2025
4.4.2025	Zercepac	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1456	7.4.2025
10.4.2025	Columvi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	11.4.2025

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10.4.2025	Flucelvax	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1879	11.4.2025
14.4.2025	Arsenic trioxide Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1427	15.4.2025
14.4.2025	Livogiva	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/20/1462	15.4.2025
14.4.2025	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	15.4.2025
14.4.2025	Oyavas	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/20/1510	16.4.2025
14.4.2025	Xenleta	Venipharm 4 Bureaux De La Colline, 92210 Saint-Cloud, France	EU/1/20/1457	17.4.2025
16.4.2025	Ovaleap	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/13/871	22.4.2025
16.4.2025	Sprycel	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/06/363	22.4.2025
16.4.2025	Targretin	H.A.C. Pharma Pericentre 2, 43 Avenue De La Cote De Nacre, Caen, 14000, France	EU/1/01/178	22.4.2025
16.4.2025	Vafseo	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37, 58638 Iserlohn, Deutschland	EU/1/23/1725	23.4.2025
17.4.2025	Alymsys	Mabxience Research SL C/ Manuel Pombo Angulo 28, 28050 Madrid, España	EU/1/20/1509	22.4.2025
17.4.2025	Enbrel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/126	23.4.2025

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17.4.2025	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	24.4.2025
23.4.2025	Ahzantive	Formycon AG 82152 Martinsried/Planegg, Deutschland	EU/1/24/1888	24.4.2025
23.4.2025	Apixaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1458	24.4.2025
23.4.2025	AQUMELDI	Proveca Pharma Limited 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland	EU/1/23/1717	24.4.2025
23.4.2025	Insulin aspart Sanofi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1447	28.4.2025
23.4.2025	Lutathera	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/17/1226	28.4.2025
23.4.2025	Lyrica	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	25.4.2025
23.4.2025	MAVENCLAD	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/17/1212	24.4.2025
23.4.2025	Neparvis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/16/1103	28.4.2025
23.4.2025	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	24.4.2025
23.4.2025	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	25.4.2025
23.4.2025	Spikevax	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/20/1507	25.4.2025

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23.4.2025	TOBI Podhaler	Viartis Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/10/652	25.4.2025
23.4.2025	Tremfya	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/17/1234	24.4.2025
23.4.2025	Upstaza	PTC Therapeutics International Limited 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/22/1653	28.4.2025
25.4.2025	Axumin	Blue Earth Diagnostics Ireland Ltd 6th Floor, 2 Grand Canal Square, Dublin 2, Ireland	EU/1/17/1186	29.4.2025
25.4.2025	Cufence	Univar Solutions B.V. Schouwburgplein 30, Rotterdam, 3012 CL, Nederland	EU/1/19/1365	30.4.2025
25.4.2025	Cuprior	Orphalan 226 Boulevard Voltaire, 75011 Paris, France	EU/1/17/1199	28.4.2025
25.4.2025	DaTSCAN	GE Healthcare B.V. De Rondom 8, 5612 AP, Eindhoven, Nederland	EU/1/00/135	28.4.2025
25.4.2025	Delytyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	30.4.2025
25.4.2025	Fabrazyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/01/188	29.4.2025
25.4.2025	IBRANCE	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1147	28.4.2025
25.4.2025	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1040	28.4.2025
25.4.2025	Koselugo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1552	28.4.2025
25.4.2025	Mixtard	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/02/231	29.4.2025

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25.4.2025	Orkambi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/15/1059	28.4.2025
25.4.2025	PREVYMIS	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/17/1245	29.4.2025
25.4.2025	Ryzneuta	Evive Biotechnology Ireland LTD 20 Kildare Street, Dublin 2, D02 T3V7, Ireland	EU/1/24/1793	2.5.2025
25.4.2025	SCENESSE	Clinuvel Europe Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/14/969	30.4.2025
25.4.2025	SOTYKTU	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1718	30.4.2025
25.4.2025	VANFLYTA	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/23/1768	29.4.2025

— **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
10.4.2025	Zostavax	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/06/341	11.4.2025
14.4.2025	Arsenic trioxide Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1427	15.4.2025
14.4.2025	Regkirona	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/21/1597	16.4.2025

— **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
2.4.2025	Omeprazole TriviumVet	omeprazole	TriviumVet DAC Unit 1N, Block 1A, Cleaboy Business Park, Old Kilmeaden Road, Waterford, X91 DEC4, Ireland	EU/2/25/336	Gastro-resistant capsule, hard	QA02BC01	3.4.2025
23.4.2025	HEPIZOVAC	Epizootic haemorrhagic disease vaccine (inactivated)	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/25/341	Suspension for injection	QI02AA	25.4.2025
23.4.2025	PRAZIVETIN	Praziquantel	VETHELLAS S.A. 51, 31 st AUGOUSTOU STREET, 412 21 LARISSA, Ελλάδα	EU/2/25/340	Premix for medicated feeding stuff	QP52AA01	28.4.2025
23.4.2025	Prevestrus vet	finrozole	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/25/338	Film-coated tablet	QG03XX90	25.4.2025
25.4.2025	Nobilis Multiriva IBm+ND+EDS	Infectious Bronchitis, Newcastle disease and Egg Drop Syndrome virus vaccine (inactivated)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/339	Emulsion for injection	QI01AA13	28.4.2025

- **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
2.4.2025	Cardalis	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/12/142	7.4.2025
2.4.2025	Clevor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/17/222	4.4.2025
2.4.2025	Coxatab	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/22/286	4.4.2025
2.4.2025	Hydrocortisone aceponate Ecuphar	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/18/230	7.4.2025
2.4.2025	Porcilis ColiClos	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/12/141	3.4.2025
2.4.2025	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	3.4.2025
2.4.2025	Simparica Trio	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain- la-Neuve, Belgique	EU/2/19/243	3.4.2025
10.4.2025	Innovax-ND-H5	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/315	11.4.2025
14.4.2025	Ingelvac CircoFLEX	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/07/079	16.4.2025
23.4.2025	Eluracat	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/23/297	25.4.2025
23.4.2025	Osurnia	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/14/170	29.4.2025
23.4.2025	Quadrisol	GROVET B.V. Centurionbaan 140, 3769 AV Soesterberg, Nederland	EU/2/97/005	28.4.2025

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23.4.2025	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	25.4.2025
23.4.2025	Suvaxyn PRRS MLV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	28.4.2025
23.4.2025	Veraflox	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/10/107	25.4.2025

— **Withdrawal 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)

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
10.4.2025	Pirsue	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/00/027	14.4.2025

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