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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2024 to 30 November 2024

(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/2024/7468)

— **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
13.11.2024	Afqlir	aflibercept	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1867	Solution for injection	S01LA05	14.11.2024
13.11.2024	Opuviz	Aflibercept	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1865	Solution for injection	S01LA05	18.11.2024
14.11.2024	ELAHERE	mirvetuximab soravtansine	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/24/1866	Concentrate for solution for infusion	L01FX26	15.11.2024
14.11.2024	Penbraya	Meningococcal groups A, C, W, Y conjugate and group B vaccine (recombinant, adsorbed)	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1871	Powder and suspension for suspension for injection	J07AH11	15.11.2024
14.11.2024	Pomalidomide Teva	pomalidomide	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/24/1868	Capsule, hard	L04AX06	15.11.2024

([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
15.11.2024	Fluad	influenza vaccine (surface antigen, inactivated, adjuvanted)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1878	Suspension for injection	J07BB02	19.11.2024
15.11.2024	Flucelvax	influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1879	Suspension for injection	J07BB02	26.11.2024
18.11.2024	Hympavzi	Marstacimab	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1874	Solution for injection	B02BX11	19.11.2024
22.11.2024	Theralugand	lutetium (^{177}Lu) chloride	Eckert & Ziegler Radiopharma GmbH Robert-Rössle-Straße 10, 13125 Berlin, Deutschland	EU/1/24/1852	Radiopharmaceutical precursor, solution	V10X	27.11.2024

— **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
4.11.2024	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	5.11.2024
4.11.2024	Farydak	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/15/1023	5.11.2024
4.11.2024	Hulio	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1319	6.11.2024
4.11.2024	Inaqovi	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/23/1756	6.11.2024
4.11.2024	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116	5.11.2024
4.11.2024	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	5.11.2024
4.11.2024	Vipdomet	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/13/843	5.11.2024
13.11.2024	Abevmy	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1515	20.11.2024
13.11.2024	Eladynos	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/22/1706	14.11.2024
13.11.2024	ELREXFIO	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1770	15.11.2024
13.11.2024	MenQuadfi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1483	14.11.2024

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
13.11.2024	Ruxience	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/20/1431	15.11.2024
13.11.2024	TAVLESSE	Instituto Grifols, S.A. Can Guasc, 2, Parets del Vallès, 08150 Barcelona, España	EU/1/19/1405	18.11.2024
13.11.2024	Vaxelis	MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, Nederland	EU/1/15/1079	14.11.2024
13.11.2024	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	14.11.2024
14.11.2024	Fingolimod Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1573	15.11.2024
14.11.2024	Fulphila	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1329	27.11.2024
14.11.2024	Givlaari	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/20/1428	19.11.2024
14.11.2024	Incruse Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/922	15.11.2024
14.11.2024	KIMMTRAK	Immunocore Ireland Limited Unit 1 Sky Business Centres, Unit 21 Block Port Tunnel Business Park, Clonshaugh, Dublin 17, Dublin, D17 FY82, Ireland	EU/1/22/1630	18.11.2024
14.11.2024	Laventair Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/899	15.11.2024
14.11.2024	Lenalidomide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/20/1490	15.11.2024

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
14.11.2024	Lumeblue	Cosmo Technologies Ltd Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/20/1470	15.11.2024
14.11.2024	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	15.11.2024
14.11.2024	Rolufta Ellipta	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/17/1174	15.11.2024
14.11.2024	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	15.11.2024
14.11.2024	Sugammadex Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1583	15.11.2024
14.11.2024	Tarceva	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/05/311	20.11.2024
14.11.2024	Tecovirimat SIGA	SIGA Technologies Netherlands B.V. Prinsenhil 29, Breda 4825 AX, Nederland	EU/1/21/1600	19.11.2024
14.11.2024	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	15.11.2024
14.11.2024	Yescarta	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/18/1299	15.11.2024
18.11.2024	Akynzeo	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	19.11.2024
18.11.2024	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	19.11.2024
18.11.2024	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	19.11.2024

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
18.11.2024	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	19.11.2024
18.11.2024	Isturisa	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/19/1407	19.11.2024
18.11.2024	Krazati	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1744	19.11.2024
18.11.2024	Lupkynis	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	19.11.2024
18.11.2024	Nevanac	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/433	19.11.2024
18.11.2024	Nilemdo	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1425	27.11.2024
18.11.2024	Nustendi	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1424	27.11.2024
18.11.2024	Orgovyx	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1642	19.11.2024
18.11.2024	Ozawade	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/21/1546	19.11.2024
18.11.2024	Praluent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/15/1031	19.11.2024
18.11.2024	Pylclari	CURIUM PET France Biopole Clermont-Limagne, 3 rue Marie Curie, 63360 Saint-Beauzire, France	EU/1/23/1746	21.11.2024
18.11.2024	Simulect	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/084	19.11.2024

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
18.11.2024	Xolair	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/05/319	19.11.2024
19.11.2024	Victoza	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/09/529	26.11.2024
22.11.2024	Anoro Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/898	25.11.2024
22.11.2024	Beovu	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1417	25.11.2024
22.11.2024	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	26.11.2024
22.11.2024	Bylvay	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/21/1566	29.11.2024
22.11.2024	Cablivi	Ablynx N.V. Technologiepark 21, 9052 Zwijnaarde, België	EU/1/18/1305	25.11.2024
22.11.2024	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	25.11.2024
22.11.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	26.11.2024
22.11.2024	SANCUSO	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/12/766	28.11.2024
22.11.2024	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/15/992	26.11.2024
22.11.2024	Scintimun	CIS bio international Boîte Postale 32, 91192 Gif-sur-Yvette, France	EU/1/09/602	27.11.2024
22.11.2024	Vaxneuvance	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1591	26.11.2024

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
22.11.2024	Yselty	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/21/1606	25.11.2024
25.11.2024	Hepcludex	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1446	26.11.2024
25.11.2024	Kevzara	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1196	26.11.2024
25.11.2024	Kisqali	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1221	26.11.2024
25.11.2024	Menveo	GSK Vaccines S.r.l. Via Fiorentina 1, 53100 Siena, Italia	EU/1/10/614	26.11.2024
25.11.2024	Orgalutran	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/00/130	27.11.2024
25.11.2024	Supemtek	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1484	28.11.2024
25.11.2024	Tevimbra	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	26.11.2024
25.11.2024	Tigecycline Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1394	26.11.2024
28.11.2024	Azacitidine Betapharm	betapharm Arzneimittel GmbH Kobelweg 95, 86156 Augsburg, Deutschland	EU/1/19/1416	4.12.2024
28.11.2024	Besponsa	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1200	29.11.2024
28.11.2024	Deferasirox Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1412	29.11.2024

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
28.11.2024	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/22/1638	3.12.2024
28.11.2024	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	29.11.2024
29.11.2024	Ameluz	Biofrontera Bioscience GmbH Hemmelrather Weg 201, 51377 Leverkusen, Deutschland	EU/1/11/740	4.12.2024
29.11.2024	Azacitidine Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1426	2.12.2024
29.11.2024	Mircera	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/07/400	3.12.2024
29.11.2024	Tasigna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/422	2.12.2024

— **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
25.11.2024	Extavia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/454	26.11.2024
25.11.2024	PreHevbri	VBI Vaccines B.V. Delflandlaan 1, Queen's Tower Office Number 714, 1062 EA Amsterdam, Nederland	EU/1/22/1641	27.11.2024

— **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
22.11.2024	BRAVECTO TriUNO	fluralaner / moxidectin / pyrantel	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/325	Chewable tablet	QP54AB52	28.11.2024
22.11.2024	DuOtic	Betamethasone acetate / Terbinafine	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/24/327	Ear gel	QS02CA90	25.11.2024
22.11.2024	VAXXON ND CLONE	Newcastle disease vaccine live	Vaxxinova International B.V Transistorweg 5, 6534 AT Nijmegen,Nederland	EU/2/24/326	lyophilisate and solvent for oculonasal suspension for chickens	QI01AD06	27.11.2024

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— **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
22.11.2024	Bovilis Nasalgen-C	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/23/294	25.11.2024
22.11.2024	Inflacam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/11/134	26.11.2024
22.11.2024	Poulvac Procerta HVT-IBD	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/23/300	26.11.2024
25.11.2024	Eluracat	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/23/297	26.11.2024
25.11.2024	Enteroporc Coli AC	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/262	26.11.2024
25.11.2024	Mometamax Ultra	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/22/289	3.12.2024
25.11.2024	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	28.11.2024
28.11.2024	CLYNAV	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/16/197	29.11.2024

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

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