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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2025 to 31 December 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/2026/402)

— **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
22.12.2025	WAYRILZ	rilzabrutinib	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/25/1974	Film-coated tablet	Pending	23.12.2025

[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.

— **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
4.12.2025	alli	Haleon Ireland Dungarvan Limited Knockbrack,Dungarvan, Co. Waterford, Ireland	EU/1/07/401	5.12.2025
4.12.2025	AQUIPTA	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1750	5.12.2025
4.12.2025	Beovu	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1417	5.12.2025
4.12.2025	Colobreathe	Essential Pharma Limited Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara CBD 1070, Malta	EU/1/11/747	17.12.2025
4.12.2025	Gazyvaro	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/14/937	5.12.2025
4.12.2025	Ibandronic acid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/798	5.12.2025
4.12.2025	Lenalidomide Krka	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/20/1519	5.12.2025
4.12.2025	NULIBRY	TMC Pharma (EU) Limited 7a Durands Court, 45 Parnell Street, Waterford, Co. Waterford, X91 P381, Ireland	EU/1/22/1684	5.12.2025
4.12.2025	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/09/599	9.12.2025
4.12.2025	Ronapreve	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1601	5.12.2025
4.12.2025	Tauvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/24/1799	8.12.2025
4.12.2025	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	9.12.2025
4.12.2025	Xolair	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/05/319	5.12.2025

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
5.12.2025	Aimovig	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1293	8.12.2025
5.12.2025	Lyvdelzi	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/24/1898	8.12.2025
5.12.2025	Palforzia	STALLERGENES 6 rue Alexis de Tocqueville, 92160 Antony, France	EU/1/20/1495	15.12.2025
5.12.2025	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	9.12.2025
5.12.2025	Soliris	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/07/393	8.12.2025
8.12.2025	AUGTYRO	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/24/1883	11.12.2025
12.12.2025	ABSIMKY	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/24/1880	15.12.2025
12.12.2025	ALTUVOCT	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/24/1824	15.12.2025
12.12.2025	Arsenic Trioxide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1398	15.12.2025
12.12.2025	Biktarvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/18/1289	17.12.2025
12.12.2025	Cystadane	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/06/379	15.12.2025
12.12.2025	DuoTrav	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/338	15.12.2025
12.12.2025	Enurev Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/789	15.12.2025
12.12.2025	Exelon	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/066	15.12.2025

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
12.12.2025	Naglazyme	BioMarin International Limited Shanbally, Ringaskiddy, County Cork P43 R298, Ireland	EU/1/05/324	16.12.2025
12.12.2025	Onbrez Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/593	15.12.2025
12.12.2025	Qaialdo	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/23/1731	16.12.2025
12.12.2025	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	15.12.2025
12.12.2025	Saphnelo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1623	15.12.2025
12.12.2025	Seffalair Spiromax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/21/1533	18.12.2025
12.12.2025	Voydeya	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/24/1792	15.12.2025
15.12.2025	Lynparza	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/14/959	16.12.2025
15.12.2025	Minjuvi	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1570	16.12.2025
15.12.2025	Vedrop	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/09/533	17.12.2025
15.12.2025	Yesafili	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/23/1751	16.12.2025
16.12.2025	Hefiya	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1287	17.12.2025
18.12.2025	Abiraterone Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/21/1553	5.1.2026
18.12.2025	Afqlir	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1867	22.12.2025
18.12.2025	Alymsys	Mabxience Research SL C/ Manuel Pombo Angulo 28, 28050 Madrid, España	EU/1/20/1509	20.12.2025

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
18.12.2025	Amsparity	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1415	19.12.2025
18.12.2025	Avastin	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/04/300	19.12.2025
18.12.2025	Avzivi	FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland	EU/1/24/1834	19.12.2025
18.12.2025	Aybintio	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1454	22.12.2025
18.12.2025	Farydak	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/15/1023	19.12.2025
18.12.2025	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	19.12.2025
18.12.2025	Lyxumia	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/12/811	19.12.2025
18.12.2025	M-M-RVAXPRO	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/06/337	19.12.2025
18.12.2025	Nexium Control	Haleon Ireland Dungarvan Limited Knockbrack,Dungarvan, Co. Waterford, Ireland	EU/1/13/860	19.12.2025
18.12.2025	Oyavas	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/20/1510	19.12.2025
18.12.2025	Pedea	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/04/284	19.12.2025
18.12.2025	Rivastigmine 1 A Pharma	1 A Pharma GmbH Industriestraße 18, 83607 Holzkirchen, Deutschland	EU/1/09/585	19.12.2025
18.12.2025	Shingrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/18/1272	19.12.2025
18.12.2025	Tremfya	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/17/1234	19.12.2025

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
18.12.2025	Vegzelma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/22/1667	22.12.2025
18.12.2025	VEYVONDI	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/18/1298	19.12.2025
18.12.2025	Vyloy	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/24/1856	19.12.2025
18.12.2025	XALKORI	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/793	19.12.2025
18.12.2025	Xerava	PAION Pharma GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/18/1312	24.12.2025
18.12.2025	Zirabev	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1344	19.12.2025
19.12.2025	Abevmy	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1515	23.12.2025
19.12.2025	Abiraterone Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1512	22.12.2025
19.12.2025	Aldurazyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/03/253	22.12.2025
19.12.2025	Kevzara	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1196	22.12.2025
19.12.2025	Kisqali	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1221	22.12.2025
19.12.2025	Levetiracetam Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/712	22.12.2025
19.12.2025	Mayzent	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1414	26.12.2025

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
19.12.2025	Mirvaso	Galderma International Tour Europlaza, 20 avenue André Prothin, La Défense 4, La Défense Cedex 92927, France	EU/1/13/904	22.12.2025
19.12.2025	Mvasi	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/17/1246	23.12.2025
19.12.2025	PHEBURANE	Eurocept International BV Trapgans 5, 1244 RL Ankeveen, Nederland	EU/1/13/822	23.12.2025
19.12.2025	Qdenga	Takeda Pharmaceuticals International AG Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, Co. Dublin, D02 HW68, Ireland	EU/1/22/1699	29.12.2025
19.12.2025	Seebri Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/788	22.12.2025
19.12.2025	Teriparatide SUN	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87, 2132JH Hoofddorp, Nederland	EU/1/22/1697	5.1.2026
19.12.2025	Topotecan Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/10/633	22.12.2025
19.12.2025	Voriconazole Hikma	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó n.º 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal	EU/1/15/1004	22.12.2025
19.12.2025	Votrient	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/628	22.12.2025

— **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
4.12.2025	Granupas	Eurocept International B.V. Trapgans 5, 1244 RL Ankeveen, Nederland	EU/1/13/896	10.12.2025
5.12.2025	Ronapreve	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1601	8.12.2025

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
15.12.2025	ABSIMKY	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/24/1880	16.12.2025
18.12.2025	Lyxumia	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/12/811	19.12.2025
18.12.2025	Mimpara	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/04/292	7.1.2026
19.12.2025	Copiktra	Secura Bio Limited 32 Molesworth Street, Dublin 2 D02 Y512, Co. Dublin, Ireland	EU/1/21/1542	5.1.2026

— **Suspension of a marketing authorisation** (Article 20 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
9.12.2025	Oxbryta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1622	10.12.2025

— **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
4.12.2025	Vaxxinact H5	Avian influenza vaccine (subunit recombinant)	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/25/356	Emulsion for injection	QI01AA23	8.12.2025
18.12.2025	ECOVAXXIN MS	Mycoplasma synoviae vaccine (live)	Eco Animal Health Europe Ltd 6th Floor, South Bank House, Barrow Street, Dublin 4 D04 TR29, Ireland	EU/2/25/357	Eye drops, suspension	QI01AE03	22.12.2025

— **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
18.12.2025	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	22.12.2025
18.12.2025	Credelio Plus	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/21/271	22.12.2025
18.12.2025	Enteroporc Coli AC	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/262	19.12.2025
18.12.2025	FRONTPRO	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/19/240	19.12.2025
18.12.2025	Kriptazen	Virbac 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	EU/2/18/234	22.12.2025
18.12.2025	Librela	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/261	19.12.2025
18.12.2025	Lotimax	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/24/311	22.12.2025
18.12.2025	Melosus	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/10/116	22.12.2025
18.12.2025	YURVAC RHD	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/23/298	23.12.2025
18.12.2025	Zenalpha	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/21/279	19.12.2025
22.12.2025	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	5.1.2026
22.12.2025	Vectormune FP ILT + AE	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/20/250	1.1.2026

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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