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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2024 to 31 December 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/2025/476)

— **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
12.12.2024	ABSIMKY	Ustekinumab	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/24/1880	Concentrate for solution for infusion Solution for injection in a pre-filled syringe	L04AC05	13.12.2024
12.12.2024	Eltrombopag Viatris	eltrombopag	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/24/1869	Film-coated tablet	B02BX05	13.12.2024
12.12.2024	IMULDOSA	ustekinumab	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1872	Concentrate for solution for infusion Solution for injection	L04AC05	16.12.2024
13.12.2024	Alhemo	concizumab	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/24/1881	Solution for injection	B02BX10	16.12.2024
19.12.2024	Buprenorphine Neuraxpharm	buprenorphine	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1809	Sublingual film	N07BC01	20.12.2024

[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.

— **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
16.12.2024	Syfovre	Apellis Europe B.V. Piet Heinkade 55, Amsterdam, Noord-Holland 1019 GM, Nederland	-	19.12.2024
19.12.2024	Masitinib AB Science	AB Science 3 avenue George V, 75008 Paris, France	-	10.1.2025

— **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
4.12.2024	Defitelio	Gentium S.r.I. Piazza XX Settembre, 2, 22079 Villa Guardia (CO), Italia	EU/1/13/878	5.12.2024
4.12.2024	Hemgenix	CSL Behring GmbH D-35041 Marburg, Deutschland	EU/1/22/1715	10.12.2024
4.12.2024	Hexacima	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/13/828	5.12.2024
4.12.2024	Hexyon	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/13/829	5.12.2024
4.12.2024	Hyftor	Plusultra pharma GmbH Fritz-Vomfelde-Str. 36, 40547 Düsseldorf, Deutschland	EU/1/23/1723	12.12.2024
4.12.2024	Vevizye	Laboratoires Thea 12 Rue Louis Bleriot, 63100 Clermont-Ferrand, France	EU/1/24/1857	5.12.2024
4.12.2024	Xeljanz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1178	6.12.2024
6.12.2024	Cerdelga	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/14/974	10.12.2024
9.12.2024	Apretude	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	10.12.2024

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
9.12.2024	Feraccru	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/15/1075	13.12.2024
9.12.2024	Olanzapine Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/08/475	11.12.2024
9.12.2024	Tegsedi	Akcea Therapeutics Ireland Ltd St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland	EU/1/18/1296	10.12.2024
11.12.2024	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/09/599	13.12.2024
12.12.2024	Abiraterone Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1571	16.12.2024
12.12.2024	Alimta	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/290	17.12.2024
12.12.2024	Armisarte	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/15/1063	16.12.2024
12.12.2024	BIMERVAX	Hipra Human Health, S.L.U. Avda. la Selva, 135, 17170 Amer (Girona), España	EU/1/22/1709	13.12.2024
12.12.2024	Bridion	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/466	13.12.2024
12.12.2024	Cinacalcet Accordpharma	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1429	13.12.2024
12.12.2024	Dengvaxia	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/18/1338	16.12.2024
12.12.2024	Hukyndra	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/21/1589	13.12.2024
12.12.2024	Imlygic	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1064	13.12.2024

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
12.12.2024	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	16.12.2024
12.12.2024	Kyprolis	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1060	13.12.2024
12.12.2024	Nintedanib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1803	13.12.2024
12.12.2024	Opdualag	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1679	16.12.2024
12.12.2024	Pemetrexed Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1071	16.12.2024
12.12.2024	Prometax	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/98/092	18.12.2024
12.12.2024	Refixia	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1193	16.12.2024
12.12.2024	Rivastigmine HEXAL	Hexal AG Industriestraße 25, 83607 Holzkirchen, Deutschland	EU/1/09/589	13.12.2024
12.12.2024	Sevelamer carbonate Winthrop	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/14/952	16.12.2024
12.12.2024	Skytrofa	Ascendis Pharma Endocrinology Division A/S Tuborg Boulevard 12, 2900 Hellerup, Danmark	EU/1/21/1607	13.12.2024
12.12.2024	Spravato	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	16.12.2024
12.12.2024	Tepkinly	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	16.12.2024
12.12.2024	Tibsovo	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France	EU/1/23/1728	13.12.2024

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
12.12.2024	Toujeo	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	16.12.2024
12.12.2024	Valdoxan	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France	EU/1/08/499	16.12.2024
12.12.2024	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	16.12.2024
12.12.2024	Vueway	Bracco Imaging SPA Via Egidio Folli, 50 20134 Milano, Italia	EU/1/23/1773	13.12.2024
12.12.2024	Zykadia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/15/999	17.12.2024
13.12.2024	CellCept	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/96/005	16.12.2024
13.12.2024	Evkeeza	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/21/1551	16.12.2024
13.12.2024	Teriflunomide Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/22/1698	16.12.2024
13.12.2024	Trepulmix	SciPharm Sàrl 7, Fausermillen, 6689 Mertert, Luxembourg	EU/1/19/1419	17.12.2024
16.12.2024	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	17.12.2024
19.12.2024	Azacitidine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1413	20.12.2024
19.12.2024	Cinacalcet Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/15/1054	20.12.2024

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
19.12.2024	Erbitux	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/04/281	20.12.2024
19.12.2024	Erelzi	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1195	7.1.2025
19.12.2024	Exelon	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/066	7.1.2025
19.12.2024	Fluad Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/20/1433	20.12.2024
19.12.2024	Libmyris	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/21/1590	20.12.2024
19.12.2024	LIBTAYO	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/19/1376	20.12.2024
19.12.2024	Litak	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/04/275	20.12.2024
19.12.2024	Lyrica	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	7.1.2025
19.12.2024	Omvoh	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1736	20.12.2024
19.12.2024	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	20.12.2024
19.12.2024	Palforzia	STALLERGENES 6 rue Alexis de Tocqueville, 92160 Antony, France	EU/1/20/1495	20.12.2024
19.12.2024	Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/16/1115	20.12.2024
19.12.2024	Relistor	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/08/463	7.1.2025

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
19.12.2024	Renvela	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/09/521	20.12.2024
19.12.2024	Rivaroxaban Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/21/1588	20.12.2024
19.12.2024	Rivastigmine 1 A Pharma	1 A Pharma GmbH Industriestraße 18, 83607 Holzkirchen, Deutschland	EU/1/09/585	23.12.2024
19.12.2024	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	20.12.2024
19.12.2024	Sitagliptin/ Metformin hydrochloride Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1619	20.12.2024
19.12.2024	TAGRISSO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1086	20.12.2024
19.12.2024	Trazimera	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1295	20.12.2024
19.12.2024	Vabysmo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1683	20.12.2024
19.12.2024	Vidaza	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/08/488	20.12.2024
19.12.2024	YERVOY	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/698	20.12.2024

— **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
13.12.2024	Alofisel	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/17/1261	13.12.2024

— **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
19.12.2024	Carprofen Orion	carprofen	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/24/328	Chewable tablet Solution for injection	QM01AE91	20.12.2024

— **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
19.12.2024	Daxocox	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/21/270	28.12.2024
19.12.2024	Equisolon	Le Vet B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/14/161	23.12.2024
19.12.2024	Locatim	MELCHIOR SANTE ANIMALE 5 Rue Victor Hugo, 69002 Lyon, France	EU/2/99/011	20.12.2024
19.12.2024	Simparica Trio	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/243	20.12.2024

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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