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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2026 to 30 June 2026

(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/2026/3946)

— **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
4.6.2026	Retsevmo	selpercatinib	Eli Lilly Nederland B.V. Orteliuslaan 1000, 3528 BD Utrecht, Nederland	EU/1/20/1527	Capsule, hard	L01EX22	5.6.2026
19.6.2026	Cenrifki	tolebrutinib	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/25/2011	Film-coated tablet	L04AA62	22.6.2026
19.6.2026	Palbociclib Viatris	palbociclib	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/26/2039	Film-coated tablet	L01EF01	22.6.2026
19.6.2026	Redemplo	plozasiran	Arrowhead Pharmaceuticals Ireland Limited One Spencer Dock, North Wall Quay, Dublin 1, D01 X9R7, Ireland	EU/1/26/2041	Solution for injection	Pending	22.6.2026
19.6.2026	Rexatilux	ranibizumab	Intas Third Party Sales 2005, S.L. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6a Planta, 08039, Barcelona, España	EU/1/26/2043	Solution for injection Solution for injection in a pre-filled syringe	S01LA04	25.6.2026

([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
30.6.2026	Itvisma	onasemnogene abeparvovec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/26/2038	Solution for injection	M09AX09	1.7.2026

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— **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
12.6.2026	Iloperidone Vanda Pharmaceuticals	Vanda Pharmaceuticals Netherlands B.V. Basisweg 10, 1043 AP Amsterdam, Nederland	-	18.6.2026

— **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
3.6.2026	Lojuxta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/13/851	5.6.2026
4.6.2026	Ahzantive	Formycon AG 82152 Martinsried/Planegg, Deutschland	EU/1/24/1888	8.6.2026
4.6.2026	Anzupgo	LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/24/1851	8.6.2026
4.6.2026	Cholestagel	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/03/268	9.6.2026
4.6.2026	Enbrel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/126	5.6.2026
4.6.2026	JEMPERLI	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/21/1538	9.6.2026
4.6.2026	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	5.6.2026
4.6.2026	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	5.6.2026
4.6.2026	Zejula	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/17/1235	9.6.2026

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
8.6.2026	Aucatzyl	Autolus GmbH Im Schwarzenbach 4, 79576 Weil am Rhein, Deutschland	EU/1/25/1951	9.6.2026
8.6.2026	Pirfenidone Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/22/1707	9.6.2026
11.6.2026	Alkindi	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/17/1260	16.6.2026
11.6.2026	Aripiprazole Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1009	12.6.2026
11.6.2026	Doptelet	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/19/1373	18.6.2026
11.6.2026	Elaprase	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/06/365	15.6.2026
11.6.2026	Emtricitabine/ Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1133	12.6.2026
11.6.2026	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	30.6.2026
11.6.2026	Qoyvolma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/25/1925	13.6.2026
11.6.2026	Repaglinide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/743	12.6.2026
11.6.2026	Repaglinide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/530	12.6.2026
11.6.2026	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	12.6.2026

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
11.6.2026	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	22.6.2026
11.6.2026	Voxzogo	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/21/1577	22.6.2026
12.6.2026	Alkindi	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/17/1260	16.6.2026
12.6.2026	Dazublys	CuraTeQ Biologics (Malta) Limited Vault 14 Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta	EU/1/25/1949	19.6.2026
12.6.2026	Dyrupeg	CuraTeQ Biologics (Malta) Limited Vault 14 Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta	EU/1/25/1914	19.6.2026
12.6.2026	Faslodex	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/03/269	15.6.2026
12.6.2026	Lorviqua	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	15.6.2026
12.6.2026	Rezzayo	Mundipharma GmbH De-Saint-Exupery-Strasse 10, 60549 Frankfurt Am Main, Deutschland	EU/1/23/1775	15.6.2026
12.6.2026	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	15.6.2026
12.6.2026	TALVEY	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1748	15.6.2026
12.6.2026	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	15.6.2026
12.6.2026	Xbryk	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1889	17.6.2026
12.6.2026	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	15.6.2026

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
12.6.2026	Zefylti	CuraTeQ Biologics (Malta) Limited Vault 14 Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta	EU/1/24/1899	19.6.2026
19.6.2026	Alunbrig	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/18/1264	23.6.2026
19.6.2026	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	22.6.2026
19.6.2026	Columvi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	22.6.2026
19.6.2026	Constella	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/12/801	22.6.2026
19.6.2026	Fluenz	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1816	22.6.2026
19.6.2026	Gardasil 9	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1007	22.6.2026
19.6.2026	Gotenfia	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/2009	23.6.2026
19.6.2026	HETRONIFLY	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1870	22.6.2026
19.6.2026	Icandra	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/484	22.6.2026
19.6.2026	Inaqovi	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/23/1756	23.6.2026
19.6.2026	Kesimpta	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/21/1532	22.6.2026

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
19.6.2026	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	22.6.2026
19.6.2026	Maviret	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/17/1213	22.6.2026
19.6.2026	Memantine Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/13/827	22.6.2026
19.6.2026	Mysimba	Orexigen Therapeutics Ireland Limited 9-10 Fenian Street, Dublin 2, D02 RX24, Ireland	EU/1/14/988	22.6.2026
19.6.2026	Ngenla	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1617	22.6.2026
19.6.2026	Ontozry	Angelini Pharma S.p.A Viale Amelia 70, 00181 Rome, Italia	EU/1/21/1530	22.6.2026
19.6.2026	Opzelura	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/23/1726	23.6.2026
19.6.2026	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	22.6.2026
19.6.2026	Palynziq	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/19/1362	29.6.2026
19.6.2026	Poteligeo	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/18/1335	23.6.2026
19.6.2026	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/22/1638	3.7.2026
19.6.2026	Rezdiffra	Madrigal Pharmaceuticals EU Limited 1 Castlewood Avenue, Dublin, D06 H685, Ireland	EU/1/25/1962	22.6.2026
19.6.2026	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	22.6.2026

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
19.6.2026	Rizmoic	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/18/1291	2.7.2026
19.6.2026	Skyrizi	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1361	22.6.2026
19.6.2026	Spherox	CO.DON GmbH Deutscher Platz 5d, 04103 Leipzig, Deutschland	EU/1/17/1181	30.6.2026
19.6.2026	Vipdomet	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/13/843	23.6.2026
19.6.2026	Zessly	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1280	23.6.2026
19.6.2026	Zomarist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/483	22.6.2026
22.6.2026	Trodelvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/21/1592	23.6.2026
25.6.2026	ADVATE	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/03/271	26.6.2026
25.6.2026	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	26.6.2026
25.6.2026	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	26.6.2026
25.6.2026	Erbitux	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/04/281	26.6.2026
25.6.2026	Eucreas	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/425	26.6.2026
25.6.2026	Eydenzelt	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1895	30.6.2026

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
25.6.2026	Lokelma	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1173	26.6.2026
25.6.2026	Olanzapine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/427	26.6.2026
25.6.2026	Rimmyrah	QILU PHARMA SPAIN S.L. Paseo de la Castellana 40, planta 8, 28046 Madrid, España	EU/1/23/1779	26.6.2026
25.6.2026	Sugammadex Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1583	26.6.2026
25.6.2026	Teysuno	Nordic Group B.V. Siriusdreef 41, 2132 WT Hoofddorp, Nederland	EU/1/11/669	29.6.2026
25.6.2026	Trimbow	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/17/1208	26.6.2026
25.6.2026	Truqap	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1820	26.6.2026
25.6.2026	Yescarta	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/18/1299	30.6.2026
25.6.2026	Zoledronic acid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/13/834	26.6.2026
26.6.2026	Levetiracetam Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/713	29.6.2026
26.6.2026	Revlimid	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/391	29.6.2026
26.6.2026	Tresiba	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/12/807	4.7.2026

— **Modification 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
19.6.2026	Hetlioz	Vanda Pharmaceuticals Netherlands B.V. Basisweg 10, 1043 AP Amsterdam, Nederland	EU/1/15/1008	23.6.2026

— **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
12.6.2026	Qoyvolma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/25/1925	16.6.2026

— **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
5.6.2026	CLYNAV	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/16/197	8.6.2026
5.6.2026	Solensia	Zoetis Belgium SA rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	10.6.2026

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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