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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2024 to 30 June 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/2024/4646)

— **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
3.6.2024	Fluenz	Influenza vaccine (live attenuated, nasal)	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1816	Nasal spray, suspension	J07BB03	4.6.2024
17.6.2024	ALTUVOCT	efanesoctocog alfa	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/24/1824	Powder and solvent for solution for injection	B02BD02	18.6.2024
17.6.2024	Sirturo	bedaquiline	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/901	Tablet	J04AK05	18.6.2024
17.6.2024	Truqap	capivasertib	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1820	Film-coated tablet	L01EX27	18.6.2024
20.6.2024	FRUZAQLA	fruquintinib	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/24/1827	Capsule, hard	L01EK	25.6.2024

([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.

20.6.2024	Tofidence	tocilizumab	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/24/1825	Concentrate for solution for infusion	L04AC07	21.6.2024
20.6.2024	Wezenla	Ustekinumab	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/24/1823	Concentrate for solution for infusion Solution for injection Solution for injection in a pre-filled syringe	L04AC05	22.6.2024
27.6.2024	Eribulin Baxter	eribulin	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/24/1819	Solution for injection	L01XX41	1.7.2024
27.6.2024	JERAYGO	aprocitentan	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/24/1818	Film-coated tablet	C02KN01	28.6.2024
27.6.2024	Obgemsa	Vibegron	PIERRE FABRE MEDICAMENT Les Cauquillous, 81500 Lavaur, France	EU/1/24/1822	Film-coated tablet	G04BD15	28.6.2024
27.6.2024	Rybrevant	amivantamab	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	Concentrate for solution for infusion	L01FX18	28.6.2024
28.6.2024	IXCHIQ	Chikungunya vaccine (live)	Valneva Austria GmbH Campus Vienna Biocenter 3, 1030 Wien, Österreich	EU/1/24/1828	Powder and solvent for solution for injection	Pending	28.6.2024

— **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
6.6.2024	Alecensa	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/16/1169	7.6.2024
6.6.2024	Cinqaero	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/16/1125	11.6.2024
6.6.2024	Efavirenz/Emtricitabine/Tenofovir disoproxil Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1263	17.6.2024
6.6.2024	Fasenra	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1252	7.6.2024
6.6.2024	Lymphoseek	Navidea Biopharmaceuticals Europe Ltd. Kilminion South, Ballinroad, Dungarvan, Co. Waterford, X35 WP70, Ireland	EU/1/14/955	7.6.2024
6.6.2024	Pedmarqsi	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/23/1734	7.6.2024
6.6.2024	Ritonavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1242	7.6.2024
6.6.2024	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	7.6.2024
6.6.2024	Sunlenca	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/22/1671	7.6.2024
6.6.2024	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508	10.6.2024
6.6.2024	Tepmetko	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/21/1596	10.6.2024
6.6.2024	Twynsta	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/10/648	17.6.2024

6.6.2024	Veltassa	Vifor Fresenius Medical Care Renal Pharma France 100-101 terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/17/1179	7.6.2024
10.6.2024	AMGLIDIA	AMMTeK 8 rue campagne première, 75014 Paris, France	EU/1/18/1279	12.6.2024
10.6.2024	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	11.6.2024
10.6.2024	Respreeza	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/15/1006	26.6.2024
10.6.2024	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	11.6.2024
13.6.2024	Atazanavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1091	14.6.2024
13.6.2024	Darunavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	14.6.2024
13.6.2024	Inbrija	Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/19/1390	14.6.2024
13.6.2024	Lopinavir/Ritonavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1067	14.6.2024
13.6.2024	Ritonavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1242	14.6.2024
13.6.2024	TALVEY	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1748	14.6.2024
13.6.2024	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	14.6.2024
13.6.2024	Telmisartan Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/10/639	14.6.2024

17.6.2024	Eviplera	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/11/737	18.6.2024
17.6.2024	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	18.6.2024
17.6.2024	Galafold	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/15/1082	19.6.2024
17.6.2024	Giotrif	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/13/879	18.6.2024
17.6.2024	Givlaari	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/20/1428	18.6.2024
17.6.2024	Kinpeygo	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/22/1657	20.6.2024
17.6.2024	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	18.6.2024
17.6.2024	Pioglitazone Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/755	18.6.2024
17.6.2024	Rasagiline Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1090	18.6.2024
17.6.2024	Renagel	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/99/123	19.6.2024
17.6.2024	Verzenios	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1307	18.6.2024
17.6.2024	Vfend	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/212	18.6.2024
17.6.2024	Xultophy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/14/947	19.6.2024
17.6.2024	Yentreve	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/280	18.6.2024

17.6.2024	Zometa	Phoenix Labs Unlimited Company Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland	EU/1/01/176	18.6.2024
20.6.2024	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	26.6.2024
20.6.2024	Abiraterone Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1571	21.6.2024
20.6.2024	Bridion	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/466	24.6.2024
20.6.2024	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	21.6.2024
20.6.2024	CONTROLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/515	25.6.2024
20.6.2024	Cymbalta	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/296	25.6.2024
20.6.2024	Duloxetine Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/972	24.6.2024
20.6.2024	Ifirmacombi	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/673	26.6.2024
20.6.2024	Kesimpta	Novartis Ireland Limited Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland	EU/1/21/1532	21.6.2024
20.6.2024	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	21.6.2024
20.6.2024	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	21.6.2024
20.6.2024	Olanzapine Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/08/475	21.6.2024

20.6.2024	PANTOZOL Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/517	25.6.2024
20.6.2024	SOMAC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/516	25.6.2024
20.6.2024	Spravato	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	24.6.2024
20.6.2024	Tivicay	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/13/892	21.6.2024
20.6.2024	TOBI Podhaler	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/10/652	21.6.2024
20.6.2024	Vabysmo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1683	21.6.2024
20.6.2024	Voriconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/835	21.6.2024
20.6.2024	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	28.6.2024
20.6.2024	Voxzogo	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/21/1577	24.6.2024
20.6.2024	Xaluprine	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, Ireland	EU/1/11/727	21.6.2024
20.6.2024	Xerava	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/18/1312	24.6.2024
20.6.2024	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/13/846	21.6.2024
20.6.2024	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	21.6.2024

20.6.2024	Zyclara	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/12/783	24.6.2024
20.6.2024	Zydelig	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/14/938	21.6.2024
27.6.2024	Byetta	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/06/362	28.6.2024
27.6.2024	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	28.6.2024
27.6.2024	Mepact	Takeda France SAS 112 avenue Kléber, 75116 Paris, France	EU/1/08/502	2.7.2024
27.6.2024	Nucala	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/15/1043	1.7.2024
27.6.2024	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	28.6.2024
27.6.2024	Stribild	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/830	28.6.2024
27.6.2024	Tavneos	Vifor Fresenius Medical Care Renal Pharma France 100-101 terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/21/1605	28.6.2024
27.6.2024	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/918	28.6.2024
27.6.2024	Xospata	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/19/1399	28.6.2024
27.6.2024	Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/12/779	28.6.2024

28.6.2024	Cabazitaxel Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1448	1.7.2024
28.6.2024	CRYSVITA	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	2.7.2024
28.6.2024	Dovprela	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1437	1.7.2024
28.6.2024	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	1.7.2024
28.6.2024	Edistride	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1052	1.7.2024
28.6.2024	Emtricitabine/Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1133	1.7.2024
28.6.2024	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/884	1.7.2024
28.6.2024	Isturisa	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/19/1407	1.7.2024
28.6.2024	Kineret	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/02/203	9.7.2024
28.6.2024	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	1.7.2024
28.6.2024	Matever	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/11/711	3.7.2024
28.6.2024	Relvar Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/13/886	1.7.2024

28.6.2024	Revinty Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/929	1.7.2024
28.6.2024	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/05/330	2.7.2024
28.6.2024	Supemtek	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/20/1484	1.7.2024
28.6.2024	TAGRISSO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1086	1.7.2024
28.6.2024	Zonisamide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1093	1.7.2024

— **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
6.6.2024	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, D02 R296, Ireland	EU/1/18/1290	7.6.2024
10.6.2024	Lymphoseek	Navidea Biopharmaceuticals Europe Ltd. Kilminion South, Ballinroad, Dungarvan, Co. Waterford, X35 WP70, Ireland	EU/1/14/955	13.6.2024
28.6.2024	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	4.7.2024

— **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
6.6.2024	Arti-Cell Forte	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/18/228	7.6.2024
6.6.2024	Coxevac	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/10/110	7.6.2024

6.6.2024	Tessie	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/21/276	7.6.2024
13.6.2024	Eurican Herpes 205	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/01/029	17.6.2024
13.6.2024	Versican Plus Pi	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/168	18.6.2024

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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