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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 August 2025 to 31 August 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/2025/5097)

— **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
11.8.2025	Vivlipeg	pegfilgrastim	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/25/1967	Solution for injection	L03AA13	1.9.2025
14.8.2025	Eiyzey	aflibercept	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/25/1963	Solution for injection	S01LA05	19.8.2025
14.8.2025	Ogsiveo	nirogacestat	SpringWorks Therapeutics Ireland Limited Hamilton House, 28 Fitzwilliam Place, Dublin 2, D02 P283, Ireland	EU/1/25/1932	Film-coated tablet	L01XX81	18.8.2025
14.8.2025	Usymro	ustekinumab	ELC Group s.r.o. Pobrezni 394/12, Karlin, 186 00 Praha 8, Česká republika	EU/1/25/1957	Concentrate for solution for infusion Solution for injection Solution for injection in a pre-filled syringe	L04AC05	26.8.2025

([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.

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
14.8.2025	Vgenfli	aflibercept	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/25/1961	Solution for injection	S01LA05	19.8.2025
18.8.2025	Afiveg	aflibercept	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1965	Solution for injection	S01LA05	22.8.2025
18.8.2025	MYNZEPLI	aflibercept	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Ireland	EU/1/25/1964	Solution for injection	S01LA05	20.8.2025
18.8.2025	Rezdiffra	Resmetirom	Madrigal Pharmaceuticals EU Limited 1 Castlewood Avenue, Dublin, D06 H685, Ireland	EU/1/25/1962	Film-coated tablet	A05BA11	19.8.2025
19.8.2025	Emtricitabine/ Rilpivirine/ Tenofovir Alafenamide Viatris	emtricitabine / rilpivirine / tenofovir alafenamide	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/25/1966	Film-coated tablet	J05AR19	21.8.2025
21.8.2025	Imreplys	sargramostim	Partner Therapeutics Ltd. 28-32 Pembroke Street Upper, Dublin 2, D02NT28, Ireland	EU/1/25/1924	Powder for solution for injection	L03AA09	8.9.2025
22.8.2025	Nintedanib Viatris	nintedanib	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/25/1959	Capsule, soft	L01E09	25.8.2025

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
25.8.2025	Yeytuo	lenacapavir	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/25/1976	Film-coated tablet Solution for injection	J05AX31	25.8.2025
25.8.2025	Zemcelpro	dorocubicel / allogeneic umbilical cord-derived CD34- cells, non-expanded	Cordex Biologics International Limited 5th Floor, Block E, Iveagh Court, Harcourt Road, Dublin, Ireland	EU/1/25/1960	Dispersion for infusion	B05AX04	26.8.2025

— **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
21.8.2025	Kinselby	4SC AG Fraunhoferstraße 22, 82152 Planegg-Martinsried, Deutschland	-	28.8.2025

— **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
4.8.2025	Beyfortus	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/22/1689	9.8.2025
4.8.2025	Bortezomib Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1114	5.8.2025
4.8.2025	Clopidogrel Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/08/465	5.8.2025
4.8.2025	IMJUDO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1713	5.8.2025
4.8.2025	INCRELEX	Esteve Pharmaceuticals S.A. Passeig de La Zona Franca 109 Planta 4, 08038 Barcelona, España	EU/1/07/402	5.8.2025
4.8.2025	Nplate	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/08/497	5.8.2025
4.8.2025	Nyvepria	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/20/1486	5.8.2025
4.8.2025	Oxlumo	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/20/1496	5.8.2025
4.8.2025	Sitagliptin/ Metformin hydrochloride Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1661	5.8.2025

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
4.8.2025	Skilarence	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/17/1201	19.8.2025
4.8.2025	Symkevi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/18/1306	13.8.2025
4.8.2025	Tenkasi	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/989	5.8.2025
4.8.2025	Yorvipath	Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12, DK-2900 Hellerup, Danmark	EU/1/23/1766	6.8.2025
6.8.2025	Fampyra	Merz Therapeutics GmbH Eckenheimer Landstraße 100, 60318 Frankfurt Am Main, Deutschland	EU/1/11/699	8.8.2025
6.8.2025	Lemtrada	Sanofi Belgium Leonardo Da Vincilaan 19, B-1831 Diegem, België	EU/1/13/869	11.8.2025
6.8.2025	Lemtrada	Sanofi Belgium Leonardo Da Vincilaan 19, B-1831 Diegem, België	EU/1/13/869	11.8.2025
6.8.2025	Luveris	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/00/155	7.8.2025
6.8.2025	Rivaroxaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1488	7.8.2025
6.8.2025	Ruconest	Pharming Group N.V. Darwinweg 24, 2333 CR Leiden, Nederland	EU/1/10/641	7.8.2025
6.8.2025	Wezenla	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/24/1823	7.8.2025
11.8.2025	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118	22.8.2025

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
11.8.2025	Eksunbi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1858	12.8.2025
11.8.2025	TALVEY	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1748	12.8.2025
11.8.2025	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	12.8.2025
11.8.2025	Xaluprine	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/11/727	12.8.2025
14.8.2025	Brukinsa	BeOne Medicines Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/21/1576	20.8.2025
14.8.2025	Emselex	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/04/294	19.8.2025
14.8.2025	Invega	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/07/395	19.8.2025
14.8.2025	Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/10/637	20.8.2025
14.8.2025	OBIZUR	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/15/1035	18.8.2025
14.8.2025	Pyzchiva	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	19.8.2025
14.8.2025	REKAMBYS	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1482	19.8.2025
14.8.2025	Roclanda	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/20/1502	26.8.2025
14.8.2025	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	18.8.2025

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
14.8.2025	TRIXEO AEROSPHERE	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1498	18.8.2025
14.8.2025	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	19.8.2025
14.8.2025	Zinforo	Pfizer Ireland Pharmaceuticals Unlimited Company Operations Support Group, Ringaskiddy, County Cork, Ireland	EU/1/12/785	18.8.2025
18.8.2025	Arexvy	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/23/1740	19.8.2025
18.8.2025	Herceptin	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/00/145	19.8.2025
18.8.2025	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef 60, 1070 Brussel, België	EU/1/05/331	19.8.2025
21.8.2025	Diacomit	Biocodex 22 rue des Aqueducs, 94250 Gentilly, France	EU/1/06/367	22.8.2025
21.8.2025	Imnovid	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/13/850	25.8.2025
21.8.2025	Lenalidomide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/20/1490	22.8.2025
21.8.2025	Ondexxya	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1345	22.8.2025
21.8.2025	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	22.8.2025
21.8.2025	Tevimbra	BeOne Medicines Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	25.8.2025

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
22.8.2025	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	26.8.2025
22.8.2025	Alhemo	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/24/1881	25.8.2025
22.8.2025	Baqsimi	Amphastar France Pharmaceuticals Usine Saint Charles, Eragny Sur Epte, 60590 France	EU/1/19/1406	25.8.2025
22.8.2025	Clopidogrel Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/08/465	26.8.2025
22.8.2025	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/884	25.8.2025
22.8.2025	Omvoh	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1736	26.8.2025
22.8.2025	Roctavian	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/22/1668	25.8.2025
22.8.2025	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/901	25.8.2025
22.8.2025	Sugammadex Adroiq	Extrovis EU Ltd. Pátriárka utca 14., 2000, Szentendre, Magyarország	EU/1/23/1733	25.8.2025
22.8.2025	Taltz	Eli Lilly and Company (Ireland) Limited Dunderrow, Kinsale, Co. Cork, Ireland	EU/1/15/1085	25.8.2025
28.8.2025	Accofil	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/14/946	29.8.2025
28.8.2025	Enspryng	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1559	29.8.2025

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
28.8.2025	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	2.9.2025
28.8.2025	Moventig	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/14/962	29.8.2025

— **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
6.8.2025	Bortezomib Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1114	7.8.2025
11.8.2025	Biopoin	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/09/565	12.8.2025
11.8.2025	Olanzapine Apotex	Apotex Europe B.V. Baarnsche Dijk 1, 3741 LN Baarn, Nederland	EU/1/10/635	9.9.2025
11.8.2025	Stocrin	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/99/111	12.8.2025
18.8.2025	Eksunbi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1858	20.8.2025

— **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
28.8.2025	CEVAC REOMUNE	avian reovirus vaccine (inactivated)	FILAVIE 20, la Corbière ROUSSAY, 49450 SEVREMOINE, France	EU/2/25/334	Emulsion for injection	QI01AA04	29.8.2025

— **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
21.8.2025	Nobivac L4	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/12/143	22.8.2025
21.8.2025	Nobivac LoVo L4	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/23/304	22.8.2025
28.8.2025	DIVENCE IBR Marker Live	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/318	29.8.2025
28.8.2025	Eluracat	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/23/297	29.8.2025
28.8.2025	Neptra	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/246	29.8.2025
28.8.2025	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	29.8.2025
28.8.2025	Syvazul BTV 3	Laboratorios Syva S.A C/Marqués de la Ensenada16, 28004 Madrid, España	EU/2/24/332	29.8.2025
28.8.2025	Zulvac 8 Ovis	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/09/104	29.8.2025

— **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): **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
6.8.2025	Poulvac E. coli	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/140	11.8.2025

— **Withdrawal 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)

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
4.8.2025	Econor	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/98/010	6.8.2025
21.8.2025	MiPet Easecto	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/220	25.8.2025

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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