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Official Journal of the European Union

EN
C series

C/2025/6344

21.11.2025

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 October 2025 to 31 October 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/2025/6344)

— **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
17.10.2025	Winlevi	Clascoterone	Cassiopea S.p.A. Via Cristoforo Colombo 1, 20045 Lainate, Milano, Italia	EU/1/25/1927	Cream	D10AX06	21.10.2025

([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
1.10.2025	Adasuve	Ferrer Internacional S.A. Gran Via Carlos III 94, 08028 Barcelona, España	EU/1/13/823	9.10.2025
1.10.2025	Celsentri	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/07/418	2.10.2025
1.10.2025	Nuvaxovid	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/21/1618	2.10.2025
1.10.2025	Prevenar 20	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1612	2.10.2025
1.10.2025	Tivicay	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/13/892	2.10.2025
1.10.2025	Viramune	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/97/055	2.10.2025
2.10.2025	BIMERVAX	Hipra Human Health, S.L.U. Avda. la Selva, 135, 17170 Amer (Girona), España	EU/1/22/1709	6.10.2025
9.10.2025	Simponi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/09/546	10.10.2025
9.10.2025	Tofidence	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/24/1825	13.10.2025
13.10.2025	Amyvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/12/805	14.10.2025
13.10.2025	Ibandronic Acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/642	14.10.2025
13.10.2025	Juluca	ViiV Healthcare B.V. Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands	EU/1/18/1282	14.10.2025

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
13.10.2025	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	14.10.2025
13.10.2025	Lacosamide Adroiq	Extrovis EU Kft. Raktarvarosi Ut 9, Torokbalint, 2045, Magyarország	EU/1/23/1732	21.10.2025
17.10.2025	Enzalutamide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/24/1842	22.10.2025
17.10.2025	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	20.10.2025
20.10.2025	Effentora	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/441	23.10.2025
20.10.2025	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	27.10.2025
20.10.2025	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	27.10.2025
20.10.2025	Quofenix	A. Menarini - Industrie Farmaceutiche Riunite - s.r.l. Via Sette Santi 3, 50131 Florence, Italia	EU/1/19/1393	23.10.2025
20.10.2025	Tezspire	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1677	21.10.2025
20.10.2025	Tremfya	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/17/1234	21.10.2025
20.10.2025	Tyverb	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/440	21.10.2025
20.10.2025	Zyprexa Velotab	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/99/125	24.10.2025

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21.10.2025	Ganfort	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/06/340	21.10.2025
24.10.2025	Alecensa	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/16/1169	27.10.2025
24.10.2025	Brukinsa	BeOne Medicines Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/21/1576	27.10.2025
24.10.2025	Dovprela	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1437	28.10.2025
24.10.2025	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	27.10.2025
24.10.2025	Koselugo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1552	27.10.2025
24.10.2025	Pyzchiva	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	27.10.2025
24.10.2025	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	28.10.2025
24.10.2025	Tevimbra	BeOne Medicines Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	27.10.2025
24.10.2025	Usymro	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/25/1957	30.10.2025
24.10.2025	Verquvo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/21/1561	27.10.2025
24.10.2025	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	27.10.2025

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
24.10.2025	Zypadhera	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/08/479	28.10.2025
30.10.2025	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	3.11.2025
30.10.2025	Kirsty	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1506	10.11.2025
30.10.2025	Posaconazole AHCL	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1380	3.11.2025

— **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
1.10.2025	PritorPlus	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/02/215	6.10.2025
17.10.2025	Dengvaxia	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/18/1338	20.10.2025
30.10.2025	NutropinAq	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/00/164	3.11.2025

— **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
24.10.2025	Hemosyvet	Etamsylate	Axience Tour Essor, 14 Rue Scandicci, 93500 Pantin, France	EU/2/25/352	Solution for injection	Pending	27.10.2025
27.10.2025	Portela	relfovetmab	Zoetis Belgium Rue Laid Burniat 1, 1348 Ottignies-Louvain-La-Neuve, Belgique	EU/2/25/353	Solution for injection	QN02BG92	29.10.2025

— **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
9.10.2025	OvuGel	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/260	10.10.2025
13.10.2025	ArthriCox	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, H62 FH90, Ireland	EU/2/24/323	16.10.2025
24.10.2025	Emevet	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/25/343	27.10.2025
24.10.2025	Meloxidolor	Le Vet Beheer B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/13/148	27.10.2025
24.10.2025	Novaquin	Le Vet Beheer B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/15/186	29.10.2025
24.10.2025	Osurnia	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/14/170	29.10.2025
24.10.2025	Semintra	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/12/146	28.10.2025
24.10.2025	Zulvac 1+8 Bovis	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/139	30.10.2025
24.10.2025	Zulvac 1+8 Ovis	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/11/120	30.10.2025
27.10.2025	BRAVECTO TriUNO	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/325	29.10.2025
27.10.2025	EVICTO	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/19/242	28.10.2025

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27.10.2025	GUMBOHATCH	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/19/245	30.10.2025
27.10.2025	Zulvac SBV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/178	29.10.2025

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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