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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 October 2026 to 31 October 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/2026/6137)

— **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
22.10.2026	Lynavoy	linerixibat	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/26/2053	Film-coated tablet	A05AX08	30.10.2026

([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.

— **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
5.10.2026	Daxas	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/636	6.10.2026
5.10.2026	Dazparda	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/26/2029	7.10.2026
5.10.2026	ELAHERE	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/24/1866	6.10.2026
5.10.2026	Kostaive	Arcturus Therapeutics Europe B.V. Claude Debussylaan 10, 1082 MD Amsterdam, Nederland	EU/1/24/1873	12.10.2026
5.10.2026	Kovaltry	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/15/1076	7.10.2026
5.10.2026	Memantine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6ª planta, 08039 Barcelona, España	EU/1/13/880	6.10.2026
5.10.2026	Mirvaso	Galderma S.A.,the Netherlands Branch De Ruijterkade 6 1013 AA Amsterdam Nederland	EU/1/13/904	6.10.2026
5.10.2026	Tenofovir disoproxil Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1129	6.10.2026
5.10.2026	Vevzuo	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/25/1945	8.10.2026
5.10.2026	Yuvanci	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1859	7.10.2026
12.10.2026	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	13.10.2026

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
12.10.2026	Vgenfli	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/25/1961	13.10.2026
15.10.2026	Apretude	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	19.10.2026
15.10.2026	Idefirix	SERB S.A. Avenue Louise 480, 1050 Bruxelles, Belgique / Louizalaan 480, 1050 Brussel, België	EU/1/20/1471	16.10.2026
15.10.2026	IMULDOSA	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6ª planta, 08039 Barcelona, España	EU/1/24/1872	19.10.2026
15.10.2026	JEVTANA	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/11/676	16.10.2026
15.10.2026	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	16.10.2026
15.10.2026	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	20.10.2026
16.10.2026	Anzupgo	LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/24/1851	20.10.2026
16.10.2026	AYVAKYT	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/20/1473	19.10.2026
16.10.2026	Celsentri	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/07/418	19.10.2026
16.10.2026	Cerezyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/97/053	20.10.2026
16.10.2026	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	19.10.2026

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
16.10.2026	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	19.10.2026
16.10.2026	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	20.10.2026
16.10.2026	Qarziba	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1191	20.10.2026
16.10.2026	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	19.10.2026
16.10.2026	Trizivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/00/156	22.10.2026
16.10.2026	Tygacil	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/336	19.10.2026
16.10.2026	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	19.10.2026
16.10.2026	Vydura	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1645	19.10.2026
16.10.2026	WAYRILZ	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/25/1974	19.10.2026
16.10.2026	Zutectra	Biotest Pharma GmbH Landsteinerstraße 5, 63303 Dreieich, Deutschland	EU/1/09/600	20.10.2026
19.10.2026	Bemrist Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1441	20.10.2026

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
19.10.2026	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	20.10.2026
19.10.2026	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	20.10.2026
19.10.2026	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	20.10.2026
22.10.2026	Abiraterone Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1571	23.10.2026
22.10.2026	Brukinsa	BeOne Medicines Netherlands B.V. Evert van de Beekstraat 1, 104, 1118 CL Schiphol, Nederland	EU/1/21/1576	23.10.2026
22.10.2026	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	26.10.2026
22.10.2026	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	23.10.2026
22.10.2026	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	27.10.2026
22.10.2026	YERVOY	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/698	23.10.2026
23.10.2026	Besremi	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/18/1352	27.10.2026
23.10.2026	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	26.10.2026

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
23.10.2026	Ervebo	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/19/1392	26.10.2026
23.10.2026	Juluca	ViiV Healthcare B.V. Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands	EU/1/18/1282	28.10.2026
23.10.2026	Pyzchiva	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	27.10.2026
23.10.2026	Taxotere	Boryung Europe Kft. Vaci Ut 33, 1134 Budapest XIII, Magyarország	EU/1/95/002	28.10.2026
23.10.2026	Vaborem	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/18/1334	28.10.2026
23.10.2026	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	26.10.2026

— **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
16.10.2026	GHRYVELIN	Atnahs Pharma Netherlands B.V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark	EU/1/18/1337	21.10.2026
22.10.2026	Comtess	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/98/082	27.10.2026
23.10.2026	Entacapone Orion	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/708	28.10.2026
23.10.2026	Trizivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/00/156	28.10.2026

— **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
23.10.2026	Cirbloc	Porcine circovirus vaccine (inactivated)	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/26/373	Emulsion for injection	QI09AA07	26.10.2026

— **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
12.10.2026	Felpreva	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/21/277	21.10.2026
15.10.2026	Firocoxib CP-Pharma	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/25/359	20.10.2026
15.10.2026	Leucofeligen FeLV/RCP	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/09/097	22.10.2026
23.10.2026	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	27.10.2026
23.10.2026	Easotic	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/08/085	27.10.2026
23.10.2026	GALLIPRANT	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/221	27.10.2026
23.10.2026	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/14/174	26.10.2026
23.10.2026	Rabitec	Ceva Santé Animale 8 rue de Logrono, 33500 Libourne, France	EU/2/17/219	28.10.2026
23.10.2026	Vectra 3D	Ceva Santé Animale 8 rue de Logrono, 33500 Libourne, France	EU/2/13/156	26.10.2026

— **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
23.10.2026	ERAVAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/16/199	30.10.2026

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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