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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2024 to 30 September 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/2024/6277)

— **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
12.9.2024	Eksunbi	ustekinumab	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1858	Concentrate for solution for infusion Solution for injection	L04AC05	13.9.2024
19.9.2024	Anzupgo	delgocitinib	LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/24/1851	Cream	D11AH11	23.9.2024
19.9.2024	Axitinib Accord	axitinib	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1847	Film-coated tablet	L01EK01	23.9.2024
19.9.2024	Iqirvo	elafibranor	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/24/1855	Film-coated tablet	A05AX06	23.9.2024
19.9.2024	Ituxredi	Rituximab	Reddy Holding GmbH Kobelweg 95, Augsburg 86156, Deutschland	EU/1/24/1861	Concentrate for solution for infusion	L01X C02	23.9.2024
19.9.2024	KAYFANDA	Odevixibat	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/24/1854	Capsule, hard	A05AX	26.9.2024

([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.

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
19.9.2024	LOQTORZI	toripalimab	TMC Pharma (EU) Limited G24 A Arclabs Research & Innovation Centre, SETU West Campus, Carriganore, Waterford, X91 P20H, Ireland	EU/1/24/1853	Concentrate for solution for infusion	L01FF13	23.9.2024
19.9.2024	Ranibizumab Midas	ranibizumab	Midas Pharma GmbH Rheinstraße 49, D-55218 Ingelheim, Deutschland	EU/1/24/1860	Solution for injection	S01LA04	24.9.2024
19.9.2024	Tuznue	trastuzumab	Prestige Biopharma Belgium BVBA Terhulpensesteenweg 449, 3090 Overijse, België	EU/1/24/1864	Powder for concentrate for solution for infusion	L01FD01	24.9.2024
19.9.2024	Vevizye	ciclosporin	Novaliq GmbH Im Neuenheimer Feld 515, Neuenheim, 69120 Heidelberg, Deutschland	EU/1/24/1857	Eye drops, solution	S01XA18	23.9.2024
19.9.2024	Vyloy	zolbetuximab	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/24/1856	Powder for concentrate for solution for infusion	L01FX31	25.9.2024
25.9.2024	Fymskina	ustekinumab	Formycon AG Fraunhoferstraße 15, 82152 Martinsried/Planegg, Deutschland	EU/1/24/1862	Concentrate for solution for infusion Solution for injection	L04AC05	26.9.2024
25.9.2024	Otulfi	ustekinumab	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/24/1863	Concentrate for solution for infusion Solution for injection	L04AC05	26.9.2024
27.9.2024	Yuvanci	Macitentan / Tadalafil	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1859	Film-coated tablet	C02KX54	30.9.2024

— **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
6.9.2024	Abseamed	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37, 58638 Iserlohn, Deutschland	EU/1/07/412	17.9.2024
6.9.2024	Atectura Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1439	9.9.2024
6.9.2024	Dabigatran etexilate Leon Farma	Laboratorios Leon Farma S.A. C/ La Vallina s/n, Poligono Industrial Navatejera, 24193 Villaquilambre León, España	EU/1/23/1769	17.9.2024
6.9.2024	Deferasirox Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1412	9.9.2024
6.9.2024	Docetaxel Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/12/770	10.9.2024
6.9.2024	Entresto	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/15/1058	9.9.2024
6.9.2024	Filgrastim Hexal	Hexal AG Industriestraße 25, 83607 Holzkirchen, Deutschland	EU/1/08/496	9.9.2024
6.9.2024	Gazyvaro	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/14/937	9.9.2024
6.9.2024	Grastofil	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/877	9.9.2024
6.9.2024	Palforzia	STALLERGENES 6 rue Alexis de Tocqueville, 92160 Antony, France	EU/1/20/1495	13.9.2024
6.9.2024	Pritor	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/089	9.9.2024

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
6.9.2024	Rhokiinsa	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/19/1400	9.9.2024
6.9.2024	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	9.9.2024
6.9.2024	Trumenba	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1187	9.9.2024
6.9.2024	Zarzio	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/08/495	9.9.2024
6.9.2024	Zessly	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1280	11.9.2024
6.9.2024	Ziagen	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/99/112	9.9.2024
6.9.2024	Zimbus Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1440	9.9.2024
10.9.2024	Spikevax	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/20/1507	11.9.2024
12.9.2024	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	13.9.2024
12.9.2024	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090	16.9.2024
12.9.2024	Pelgraz	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/18/1313	13.9.2024
12.9.2024	Rukobia	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1518	13.9.2024
12.9.2024	Xelevia	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/382	13.9.2024

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
16.9.2024	Adtralza	Leo Pharma A/S Industriparken 55, 2750 Ballerup, Danmark	EU/1/21/1554	19.9.2024
16.9.2024	Bemrist Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1441	17.9.2024
16.9.2024	Binocrit	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/07/410	17.9.2024
16.9.2024	Enerzair Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1438	17.9.2024
16.9.2024	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	20.9.2024
16.9.2024	Irbesartan Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/576	17.10.2024
16.9.2024	Ledaga	Helsinn Birex Pharmaceuticals Ltd. Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/16/1171	18.9.2024
16.9.2024	Melatonin Neurim	RAD Neurim Pharmaceuticals EEC SARL 4 rue de Marivaux, 75002 Paris, France	EU/1/22/1694	17.9.2024
16.9.2024	Tezspire	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1677	17.9.2024
16.9.2024	Toviaz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/386	17.9.2024
19.9.2024	Amsparity	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1415	23.9.2024
19.9.2024	Arsenic Trioxide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1398	23.9.2024

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
19.9.2024	Beovu	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1417	23.9.2024
19.9.2024	CABOMETYX	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/16/1136	23.9.2024
19.9.2024	EDURANT	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/11/736	23.9.2024
19.9.2024	Epoetin alfa Hexal	Hexal AG Industriestraße 25, 83607 Holzkirchen, Deutschland	EU/1/07/411	23.9.2024
19.9.2024	Evrenzo	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1574	24.9.2024
19.9.2024	GAVRETO	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/21/1555	26.9.2024
19.9.2024	Giapreza	PAION Pharma GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/19/1384	23.9.2024
19.9.2024	Imvanex	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/13/855	19.9.2024
19.9.2024	Ivabradine Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/17/1190	23.9.2024
19.9.2024	Januvia	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/383	23.9.2024
19.9.2024	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	23.9.2024
19.9.2024	Mayzent	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1414	23.9.2024

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
19.9.2024	Neparvis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/16/1103	23.9.2024
19.9.2024	Opsumit	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/893	23.9.2024
19.9.2024	Orladeyo	Biocryst Ireland Limited Block 4, Harcourt Centre, Harcourt Road, Dublin 2, D02 HW77, Ireland	EU/1/21/1544	23.9.2024
19.9.2024	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	23.9.2024
19.9.2024	Recarbrio	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/19/1420	23.9.2024
19.9.2024	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	23.9.2024
19.9.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	24.9.2024
19.9.2024	Synagis	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/99/117	23.9.2024
19.9.2024	Ziextenzo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1327	23.9.2024
25.9.2024	Kinpeygo	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/22/1657	30.9.2024
25.9.2024	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	27.9.2024
25.9.2024	Stelara	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/08/494	26.9.2024
25.9.2024	Talmanco	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/16/1153	2.9.2024

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
25.9.2024	Talmanco	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/16/1153	26.9.2024
25.9.2024	Yuflyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/20/1513	27.9.2024
26.9.2024	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	26.9.2024
27.9.2024	Adrovance	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/06/364	3.10.2024
27.9.2024	Biopoin	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/09/565	2.10.2024
27.9.2024	Breyanzi	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1631	30.9.2024
27.9.2024	Cometriq	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/13/890	30.9.2024
27.9.2024	Dabigatran etexilate Teva	Laboratorios Leon Farma S.A. C/ La Vallina s/n, Poligono Industrial Navatejera, 24193 Villaquilambre León, España	EU/1/23/1769	1.10.2024
27.9.2024	Fampyra	Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/11/699	1.10.2024
27.9.2024	GONAL-f	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/95/001	1.10.2024
27.9.2024	Ivabradine Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1144	3.10.2024
27.9.2024	Lacosamide Adroiq	Extrovis EU Ltd. Pátriárka utca 14., 2000, Szentendre, Magyarország	EU/1/23/1732	2.10.2024
27.9.2024	MAVENCLAD	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/17/1212	30.9.2024

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
27.9.2024	Mylotarg	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1277	30.9.2024
27.9.2024	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	30.9.2024
27.9.2024	Plerixafor Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1701	30.9.2024
27.9.2024	Shingrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/18/1272	30.9.2024
27.9.2024	Tenofovir disoproxil Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1129	30.9.2024
27.9.2024	Tesavel	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/435	30.9.2024
27.9.2024	Tolucombi	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/821	3.10.2024
27.9.2024	Tyruko	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/23/1745	30.9.2024
27.9.2024	Vantavo	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/09/572	30.9.2024
27.9.2024	YERVOY	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/698	30.9.2024
30.9.2024	Myozyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/333	1.10.2024

— **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
6.9.2024	Memantine LEK	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/13/826	10.9.2024
25.9.2024	Exviera	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/14/983	26.9.2024
25.9.2024	Viekirax	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/14/982	26.9.2024
27.9.2024	Gefitinib Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/18/1321	30.9.2024

— **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
12.9.2024	Cepeloron	Spironolactone	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/24/321	Chewable tablet	Pending	13.9.2024

— **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
6.9.2024	Posatex	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/08/081	9.9.2024
6.9.2024	Profender	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/05/054	9.9.2024
12.9.2024	Rabitec	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/219	13.9.2024
19.9.2024	Brucellin Aquilon	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/22/291	25.9.2024

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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