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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 April 2024 to 30 April 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/2024/3355)

— **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
19.4.2024	Apremilast Accord	apremilast	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1796	Film-coated tablet	L04AA32	23.4.2024
19.4.2024	CARVYKTI	ciltacabtagene autoleucel	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	Dispersion for infusion	L01XL05	22.4.2024
19.4.2024	Celldemic	Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1806	Suspension for injection in pre-filled syringe (injection).	J07BB02	22.4.2024
19.4.2024	Filspari	Sparsentan	Vifor France S.A. Tour Franklin La Defense 8, 100-101 Terrasse Boieldieu, 92042 Paris La Defense Cedex, France	EU/1/23/1788	Film-coated tablet	C09XX01	23.4.2024

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 4, 7.1.2019, p. 43.

19.4.2024	Incellipan	Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1807	Suspension for injection	J07BB02	23.4.2024
19.4.2024	Nintedanib Accord	nintedanib	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1803	Capsule, soft	L01EX09	24.4.2024
19.4.2024	Pyzchiva	ustekinumab	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	Concentrate for solution for injection Solution for injection	L04AC05	24.4.2024
19.4.2024	Tizveni	tislelizumab	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/24/1797	Concentrate for solution for infusion		22.4.2024
19.4.2024	Voydeya	danicopan	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/24/1792	Film-coated tablet	L04AJ09	25.4.2024
19.4.2024	ZYNYZ	retifanlimab	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/24/1800	Concentrate for solution for infusion	L01FF10	24.4.2024
22.4.2024	Dimethyl fumarate Accord	dimethyl fumarate	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1811	Gastro-resistant capsule, hard	L04AX07	24.4.2024

22.4.2024	Dimethyl fumarate Mylan	dimethyl fumarate	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/24/1814	Gastro-resistant capsule, hard	L04AX07	22.4.2024
22.4.2024	Dimethyl fumarate Neuraxpharm	dimethyl fumarate	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1810	Gastro-resistant capsule, hard	L04AX07	22.4.2024
22.4.2024	Emblaveo	aztreonam / avibactam	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1808	Powder for concentrate for solution for infusion	J01DF51	22.4.2024

— **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
5.4.2024	Alofisel	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/17/1261	8.4.2024
5.4.2024	Clopidogrel/Acetylsalicylic acid Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	8.4.2024
5.4.2024	Entecavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1227	8.4.2024
5.4.2024	Epidyolex	Jazz Pharmaceuticals Ireland Ltd 5th Floor, Waterloo Exchange, Waterloo Road, Dublin D04 E5W7, Ireland	EU/1/19/1389	8.4.2024
5.4.2024	Febuxostat Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	8.4.2024
5.4.2024	Lacosamide UCB	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1383	8.4.2024
5.4.2024	Lokelma	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1173	8.4.2024
5.4.2024	Lorviqua	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	8.4.2024
5.4.2024	Orkambi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/15/1059	8.4.2024
5.4.2024	Perjeta	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/813	8.4.2024
9.4.2024	Anagrelide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/17/1256	10.4.2024

9.4.2024	Clopidogrel/Acetylsalicylic acid Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	10.4.2024
9.4.2024	Drovelis	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/21/1547	11.4.2024
9.4.2024	Entecavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1227	10.4.2024
9.4.2024	Febuxostat Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	10.4.2024
9.4.2024	Inhixa	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077 XX Amsterdam, Nederland	EU/1/16/1132	15.4.2024
9.4.2024	Orfadin	Swedish Orphan Biovitrum International AB 112 76 Stockholm, Sverige	EU/1/04/303	11.4.2024
9.4.2024	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	10.4.2024
9.4.2024	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	10.4.2024
9.4.2024	Prasugrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1273	10.4.2024
9.4.2024	Zalasta	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/07/415	15.4.2024
9.4.2024	Zeposia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1442	10.4.2024
9.4.2024	Zoonotic Influenza Vaccine Seqirus	Seqirus S.r.l. Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italia	EU/1/23/1761	10.4.2024
11.4.2024	Fingolimod Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1573	15.4.2024

15.4.2024	Moventig	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/14/962	17.4.2024
15.4.2024	Talzenna	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1377	16.4.2024
19.4.2024	Atazanavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1091	22.4.2024
19.4.2024	Biktarvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/18/1289	22.4.2024
19.4.2024	Bimzelx	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/21/1575	23.4.2024
19.4.2024	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	23.4.2024
19.4.2024	Emtricitabine/ Tenofovir disoproxil Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1148	22.4.2024
19.4.2024	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	23.4.2024
19.4.2024	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	22.4.2024
19.4.2024	Koselugo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1552	22.4.2024
19.4.2024	Lamivudine Teva Pharma B.V.	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/596	22.4.2024
19.4.2024	Leqvio	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1494	23.4.2024

19.4.2024	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	22.4.2024
19.4.2024	Lyxumia	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/12/811	22.4.2024
19.4.2024	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	22.4.2024
19.4.2024	Onglyza	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/545	22.4.2024
19.4.2024	Palynziq	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/19/1362	22.4.2024
19.4.2024	Pandemic influenza vaccine H5N1 AstraZeneca	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1089	22.4.2024
19.4.2024	Pluvicto	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1703	26.4.2024
19.4.2024	Potactasol	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/10/660	23.4.2024
19.4.2024	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	22.4.2024
19.4.2024	Qtern	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1108	22.4.2024
19.4.2024	Rivastigmine Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/693	25.4.2024
19.4.2024	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	22.4.2024
19.4.2024	Spedra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/13/841	23.4.2024
19.4.2024	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	22.4.2024

19.4.2024	Teriflunomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1693	24.4.2024
19.4.2024	Twinrix Adult	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/96/020	24.4.2024
19.4.2024	Twinrix Paediatric	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/97/029	24.4.2024
19.4.2024	Ultomiris	Alexion Europe SAS 103-105 Rue Anatole France, 92300 Levallois-Perret, France	EU/1/19/1371	29.4.2024
19.4.2024	Xeplion	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/11/672	22.4.2024
19.4.2024	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/13/846	25.4.2024
25.4.2024	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/02/224	26.4.2024
25.4.2024	BYANNLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1453	26.4.2024
25.4.2024	Colobreathe	Essential Pharma Limited Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara CBD 1070, Malta	EU/1/11/747	30.4.2024
25.4.2024	Granpidam	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/16/1137	26.4.2024
25.4.2024	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/12/782	26.4.2024

25.4.2024	Krazati	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1744	6.5.2024
25.4.2024	Levetiracetam Actavis Group	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/738	26.4.2024
25.4.2024	Lydisilka	Estetra SRL Rue Saint Georges 5-7, 4000 Liège, Belgique	EU/1/21/1548	26.4.2024
25.4.2024	LysaKare	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/19/1381	26.4.2024
25.4.2024	Onivyde pegylated liposomal	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes Cedex, France	EU/1/16/1130	30.4.2024
25.4.2024	Yselty	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/21/1606	29.4.2024
29.4.2024	Luxturna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1331	1.5.2024
29.4.2024	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	6.5.2024
29.4.2024	Xerava	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/18/1312	6.5.2024

— **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
19.4.2024	Telmisartan Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/719	22.4.2024

— **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
8.4.2024	Alcort	hydrocortisone aceponate	NEXTMUNE ITALY S.R.L. Via G.B. Benzoni 50, 26020 Palazzo Pignano (CR), Italia	EU/2/24/306	Cutaneous spray, solution	QD07AC16	9.4.2024
8.4.2024	Lexylan	cefalexin	Emdoka John Lijsenstraat 16, 2321 Hoogstraten, België	EU/2/24/308	Suspension for injection	QJ01DB01	10.4.2024
9.4.2024	DIVENCE PENTA	Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/307	Lyophilisate and solvent for solution for injection	QI02AH	10.4.2024
25.4.2024	Lotimax	lotilaner	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/24/311	Chewable tablet	QP53BE04	29.4.2024

— **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
8.4.2024	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	12.4.2024
8.4.2024	Chanhold	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/19/236	15.4.2024
8.4.2024	Daxocox	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/21/270	9.4.2024
8.4.2024	Draxxin	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/03/041	10.4.2024
8.4.2024	Incurin	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/018	11.4.2024
9.4.2024	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	12.4.2024
9.4.2024	Lydaxx	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/253	10.4.2024
9.4.2024	OvuGel	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/260	10.4.2024
9.4.2024	Strangvac	Intervacc AB Vastertorpsvagen 135, 129 44 Hagersten, Sverige	EU/2/21/274	10.4.2024
11.4.2024	Tulissin	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/20/252	12.4.2024
25.4.2024	Halocur	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/99/013	26.4.2024
25.4.2024	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/14/174	29.4.2024

25.4.2024	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	30.4.2024
25.4.2024	Purevax RCP	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/052	29.4.2024
25.4.2024	Senvelgo	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/23/305	29.4.2024
25.4.2024	Tulaven	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/251	26.4.2024
29.4.2024	Coliprotec F4/F18	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/16/202	30.4.2024

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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