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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 August 2024 to 31 August 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/2024/5667)

— **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
1.8.2024	ADZYNMA	rADAMTS13	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/24/1837	Powder and solvent for solution for injection	B01AD13	2.8.2024
1.8.2024	GalliaPharm	germanium (^{68}Ge) chloride / gallium (^{68}Ga) chloride	Eckert & Ziegler Radiopharma GmbH Robert-Rössle-Straße 10, 13125 Berlin, Deutschland	EU/1/24/1836	Radionuclide generator.	V09X	2.8.2024
22.8.2024	AKANTIOR	polihexanide	SIFI S.p.A. Via Ercole Patti 36, 95025 Aci Sant'Antonio (CT), Italia	EU/1/24/1840	Eye drops, solution	S01AX24	23.8.2024
22.8.2024	Balversa	erdafitinib	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1841	Film-coated tablet	L01EN01	23.8.2024
22.8.2024	Enzalutamide Viatris	enzalutamide	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/24/1842	Film-coated tablet	L02BB04	23.8.2024
22.8.2024	EURneffy	Epinephrine	ARS Pharmaceuticals IRL, Limited The Black Church, Saint Mary's Place North, Dublin 7, Co. Dublin, D07 P4AX, Ireland	EU/1/24/1846	Nasal spray, solution	C01CA24	23.8.2024
22.8.2024	mRESVIA	Single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycopro-	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/24/1849	dispersion for injection	J07BX05	23.8.2024

[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
		tein F stabilized in the prefusion conformation					
22.8.2024	Nilotinib Accord	nilotinib	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1845	Capsule, hard	L01EA03	23.8.2024
22.8.2024	Ordspono	odronextamab	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/24/1843	Solution for infusion	Pending	23.8.2024
22.8.2024	Piasky	crovalimab	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/24/1848	Solution for injection or infusion	L04AJ07	26.8.2024
22.8.2024	STEQEYMA	ustekinumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1844	Concentrate for solution for infusion Solution for injection in a pre-filled syringe	L04AC05	23.8.2024
22.8.2024	Tauvid	Flortaucipir (18F)	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/24/1799	Solution for injection	V09AX07	26.8.2024
22.8.2024	Winrevair	sotatercept	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/24/1850	Powder and solvent for solution for injection Powder for solution for injection	C02KX06	27.8.2024

— **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
1.8.2024	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118	6.8.2024
1.8.2024	Beyfortus	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/22/1689	2.8.2024
1.8.2024	Bimzelx	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/21/1575	5.8.2024
1.8.2024	Edistride	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1052	2.8.2024
1.8.2024	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	6.8.2024
1.8.2024	Noxafil	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/320	2.8.2024
1.8.2024	Reagila	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/17/1209	15.8.2024
1.8.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	5.8.2024
1.8.2024	Vosevi	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/17/1223	6.8.2024
5.8.2024	ADVATE	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/03/271	6.8.2024
5.8.2024	CAMZYOS	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1716	6.8.2024
5.8.2024	Dabigatran Etexilate Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1665	12.8.2024

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
5.8.2024	Dapagliflozin Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1721	6.8.2024
5.8.2024	Filsuvez	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/22/1652	8.8.2024
5.8.2024	Fotivda	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1215	13.8.2024
5.8.2024	Lojuxta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/13/851	8.8.2024
5.8.2024	Pegasys	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/02/221	6.8.2024
5.8.2024	Skyclarys	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/23/1786	6.8.2024
5.8.2024	Vyndaqel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/11/717	6.8.2024
9.8.2024	Actos	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/00/150	21.8.2024
9.8.2024	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	12.8.2024
9.8.2024	Xarelto	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/08/472	12.8.2024
12.8.2024	Hefiya	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1287	13.8.2024
12.8.2024	Lynparza	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/14/959	13.8.2024
12.8.2024	TRIXEO AEROSPHERE	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1498	13.8.2024
12.8.2024	Zypadhera	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/08/479	14.8.2024

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
16.8.2024	Abrysvo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1752	19.8.2024
16.8.2024	Competact	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/06/354	9.9.2024
16.8.2024	Jaypirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1738	19.8.2024
16.8.2024	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	19.8.2024
16.8.2024	Roctavian	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/22/1668	22.8.2024
16.8.2024	Spinraza	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/17/1188	19.8.2024
16.8.2024	Tepkinly	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	19.8.2024
22.8.2024	Baqsimi	Amphastar France Pharmaceuticals Usine Saint Charles, Eragny Sur Epte, 60590 France	EU/1/19/1406	23.8.2024
22.8.2024	Betmiga	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/12/809	27.8.2024
22.8.2024	Cegfila	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/19/1409	23.8.2024
22.8.2024	Clopidogrel/Acetylsalicylic acid Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	23.8.2024
22.8.2024	Copiktra	Secura Bio Limited 32 Molesworth Street, Dublin 2 D02 Y512, Co. Dublin, Ireland	EU/1/21/1542	29.8.2024

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
22.8.2024	Cresemba	Basilea Pharmaceutica Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/15/1036	23.8.2024
22.8.2024	Evenity	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1411	26.8.2024
22.8.2024	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/945	23.8.2024
22.8.2024	Instanyl	Istituto Gentili S.r.l. Via San Giuseppe Cottolengo 15, 20143 Milano, Italia	EU/1/09/531	27.8.2024
22.8.2024	Jylamvo	Oresund Pharma ApS Orient Plads 1, 2150 Nordhavn, Danmark	EU/1/17/1172	23.8.2024
22.8.2024	Jyseleca	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/20/1480	28.8.2024
22.8.2024	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	26.8.2024
22.8.2024	Quofenix	A. Menarini - Industrie Farmaceutiche Riunite - s.r.l. Via Sette Santi 3, 50131 Florence, Italia	EU/1/19/1393	27.8.2024
22.8.2024	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	23.8.2024
22.8.2024	Savene	CNX Therapeutics Ireland Limited 5th Floor Rear, Connaught House, 1 Burlington Road, Dublin 4, Ireland	EU/1/06/350	23.8.2024
22.8.2024	Signifor	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/12/753	26.8.2024
22.8.2024	Spravato	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	23.8.2024
22.8.2024	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	23.8.2024

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
22.8.2024	XALKORI	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/793	23.8.2024
26.8.2024	Arexvy	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/23/1740	27.8.2024
26.8.2024	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	27.8.2024
26.8.2024	Slenyto	RAD Neurim Pharmaceuticals EEC SARL 4 rue de Marivaux, 75002 Paris, France	EU/1/18/1318	28.8.2024
26.8.2024	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	27.8.2024
29.8.2024	Abiraterone Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1512	30.8.2024
29.8.2024	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	3.9.2024
29.8.2024	Ilaris	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/564	30.8.2024
29.8.2024	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	30.8.2024
29.8.2024	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	3.9.2024
29.8.2024	Opfolda	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/23/1737	30.8.2024
29.8.2024	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	30.8.2024

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
29.8.2024	Vyvgart	argenx BV Industriepark-Zwijnaarde 7, 9052 Gent, België	EU/1/22/1674	30.8.2024
29.8.2024	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	30.8.2024
30.8.2024	ADYNOVI	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/17/1247	3.9.2024
30.8.2024	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	2.9.2024
30.8.2024	Nordimet	Nordic Group B.V. Siriusdreef 41, 2132 WT Hoofddorp, Nederland	EU/1/16/1124	2.9.2024
30.8.2024	Riltrava Aerosphere	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1604	2.9.2024

— **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
2.8.2024	NYXTHRACIS	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/20/1485	5.8.2024

— **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
9.8.2024	DIVENCE IBR Marker Live	Bovine herpesvirus type 1 (live) vaccine	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/318	lyophilisate and solvent for emulsion for injection	QI02AD01	20.8.2024
30.8.2024	Cevac Salmune ETI K	*Salmonella enterica*, subsp. *enterica*, serovar Enteritidis; *Salmonella enterica*, subsp. *enterica*, serovar Typhimurium; and *Salmonella enterica*, subsp. *enterica*, serovar Infantis vaccine (inactivated) for chickens	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/24/320	Suspension for injection	QI01AB01	2.9.2024
30.8.2024	Porcilis PCV M Hyo ID	Porcine circovirus and porcine enzootic pneumonia vaccine (inactivated)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/319	Emulsion for injection	QI09AL08	2.9.2024

— **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
2.8.2024	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	6.8.2024
2.8.2024	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	6.8.2024
2.8.2024	Daxocox	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/21/270	5.8.2024
2.8.2024	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	5.8.2024
2.8.2024	PREVEXXION RN +HVT	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/23/302	6.8.2024
2.8.2024	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	6.8.2024
5.8.2024	Neptra	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/246	6.8.2024
5.8.2024	Stronghold Plus	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	9.8.2024
5.8.2024	Vaxxitek HVT + IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/02/032	6.8.2024
9.8.2024	PREVEXXION RN	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/254	12.8.2024
9.8.2024	Suvaxyn PRRS MLV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	12.8.2024
20.8.2024	CircoMax	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/21/281	22.8.2024
20.8.2024	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	21.8.2024

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
22.8.2024	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	23.8.2024
22.8.2024	FATROVAX RHD	FATRO S.p.A. Via Emilia 285, 40064 Ozzano dell'Emilia (BO), ITALIA	EU/2/21/275	23.8.2024
30.8.2024	Clomicalm	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/98/007	2.9.2024
30.8.2024	Vectormune ND	CEVA-Phylaxia Co. Ltd Szállás u. 5, 1107 Budapest, Magyarország	EU/2/15/188	5.9.2024

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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