IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 February 2023 to 28 February 2023

(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])

(2023/C 118/01)

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

— **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
15.2.2023	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/1/22/1711	Gastro-resistant capsule, hard	L04AX07	17.2.2023
20.2.2023	Hemgenix	etranacogene dezaparvovec	CSL Behring GmbH D-35041 Marburg, Deutschland	EU/1/22/1715	Concentrate for solution for infusion	B06	23.2.2023
20.2.2023	IMJUDO	tremelimumab	AstraZeneca AB Forskargatan 18, 151 85 Södertälje, Sverige	EU/1/22/1713	Concentrate for solution for infusion	L01FX20	23.2.2023
20.2.2023	Tremelimumab AstraZeneca	tremelimumab	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1712	Concentrate for solution for infusion	L01FX20	21.2.2023
24.2.2023	Paxlovid	Nirmatrelvir / ritonavir	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	Film-coated tablet	J05AE30	27.2.2023

— **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
3.2.2023	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/02/224	6.2.2023
3.2.2023	Bortezomib Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1114	6.2.2023
3.2.2023	Copiktra	Secura Bio Limited 32 Molesworth Street, Dublin 2 D02 Y512, Co. Dublin, Ireland	EU/1/21/1542	17.2.2023
3.2.2023	Darunavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	7.2.2023
3.2.2023	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1025	6.2.2023
3.2.2023	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	6.2.2023
3.2.2023	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	7.2.2023
3.2.2023	HALAVEN	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/11/678	8.2.2023
3.2.2023	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	17.2.2023
3.2.2023	Invanz	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/02/216	9.2.2023
3.2.2023	KANJINTI	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/18/1281	6.2.2023
3.2.2023	Levetiracetam Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/712	6.2.2023
3.2.2023	Nimvastid	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/525	14.2.2023
3.2.2023	NULIBRY	Zydus France S.A.S. Zac Les Hautes Patures, 25 Rue Des Peupliers, 92000 Nanterre, France	EU/1/22/1684	9.2.2023
3.2.2023	Orencia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/389	6.2.2023
3.2.2023	Pemetrexed Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1071	7.2.2023

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
3.2.2023	Quofenix	A. Menarini — Industrie Farmaceutiche Riunite — s.r.l. Via Sette Santi 3, 50131 Florence, Italia	EU/1/19/1393	8.2.2023
3.2.2023	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	13.2.2023
3.2.2023	Rixubis	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/14/970	9.2.2023
3.2.2023	SCENESSE	Clinuvel Europe Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/14/969	7.2.2023
3.2.2023	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	6.2.2023
3.2.2023	TRISENOX	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/02/204	7.2.2023
3.2.2023	Xagrid	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/04/295	6.2.2023
3.2.2023	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	6.2.2023
6.2.2023	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	7.2.2023
6.2.2023	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	7.2.2023
6.2.2023	Hefiya	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1287	7.2.2023
6.2.2023	Kerendia	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/21/1616	7.2.2023
6.2.2023	Tivicay	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/13/892	7.2.2023
6.2.2023	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	13.2.2023
9.2.2023	AMGLIDIA	AMMTeK 55 rue de Turbigo, 75003 Paris, France	EU/1/18/1279	14.2.2023
9.2.2023	Brukinsa	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/21/1576	10.2.2023
9.2.2023	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	13.2.2023

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15.2.2023	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	17.2.2023
15.2.2023	Fulphila	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1329	16.2.2023
15.2.2023	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	20.2.2023
15.2.2023	JEMPERLI	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	20.2.2023
15.2.2023	Lokelma	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1173	16.2.2023
15.2.2023	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	16.2.2023
15.2.2023	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	20.2.2023
15.2.2023	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	6.3.2023
15.2.2023	Semglee	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1270	16.2.2023
15.2.2023	Trodelvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/21/1592	16.2.2023
15.2.2023	Vyndaqel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/11/717	16.2.2023
15.2.2023	Zonegran	Amdipharm Limited 3 Burlington Road, Dublin 4, D04 RD68, IRELAND	EU/1/04/307	21.2.2023
20.2.2023	Aimovig	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1293	22.2.2023
20.2.2023	Calquence	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1479	21.2.2023
20.2.2023	Tractocile	Ferring Pharmaceuticals A/S Amager Strandvej 405, 2770 Kastrup, Danmark	EU/1/99/124	3.3.2023
20.2.2023	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	21.2.2023
20.2.2023	Yuflyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/20/1513	21.2.2023

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
23.2.2023	Atosiban SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/13/852	27.2.2023
23.2.2023	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	24.2.2023
23.2.2023	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	24.2.2023
23.2.2023	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	24.2.2023
23.2.2023	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090	2.3.2023
23.2.2023	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	24.2.2023
23.2.2023	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	24.2.2023
24.2.2023	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	27.2.2023
24.2.2023	Emselex	zr pharma& GmbH Hietzinger Hauptstrasse 37, 1130 Wien, Österreich	EU/1/04/294	1.3.2023
24.2.2023	Febuxostat Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	27.2.2023
24.2.2023	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	27.2.2023
24.2.2023	QINLOCK	Deciphera Pharmaceuticals (Netherlands) B.V. Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland	EU/1/21/1569	3.3.2023
24.2.2023	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	27.2.2023
24.2.2023	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	27.2.2023
24.2.2023	Ronapreve	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1601	28.2.2023

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24.2.2023	TUKYSA	Seagen B.V. Evert van de Beekstraat 1-104, 1118CL Schiphol, Nederland	EU/1/20/1526	2.3.2023
24.2.2023	Wakix	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/15/1068	27.2.2023
27.2.2023	Abilify	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/04/276	7.3.2023
27.2.2023	Aflunov	Seqirus S.r.l. Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italy	EU/1/10/658	28.2.2023
27.2.2023	Daptomycin Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1175	28.2.2023
27.2.2023	Foclivia	Seqirus S.r.l., Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italia	EU/1/09/577	28.2.2023
27.2.2023	NUBEQA	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/20/1432	28.2.2023
27.2.2023	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	28.2.2023
27.2.2023	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	28.2.2023
27.2.2023	Sprycel	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/06/363	28.2.2023
27.2.2023	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	28.2.2023
27.2.2023	Venclyxto	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/16/1138	28.2.2023
27.2.2023	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	28.2.2023

— **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
23.2.2023	Pregabalin Zentiva k.s	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1166	24.2.2023

— **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
2.2.2023	Tulissin	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/20/252	6.2.2023
3.2.2023	Forceris	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/19/235	6.2.2023
3.2.2023	Locatim	Biokema Europe Centre des Affaires des Lilas, 77 Avenue des Lilas, 64000 Pau, France	EU/2/99/011	9.2.2023
3.2.2023	Panacur AquaSol	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/135	7.2.2023
6.2.2023	Apoquel	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	7.2.2023
6.2.2023	CLYNAV	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/16/197	7.2.2023
6.2.2023	Procox	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/11/123	8.2.2023
6.2.2023	Procox	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/11/123	7.2.2023
6.2.2023	Versican Plus DHPPi/L4R	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/163	7.2.2023
9.2.2023	MiPet Easecto	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/220	14.2.2023
20.2.2023	Advocate	Bayer Animal Health GmbH D-51368 Leverkusen, Deutschland	EU/2/03/039	22.2.2023
20.2.2023	Bovela	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/176	22.2.2023
20.2.2023	GALLIPRANT	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/221	21.2.2023
20.2.2023	Suvaxyn Circo + MH RTU	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/15/190	23.2.2023
23.2.2023	Locatim	Biokema Europe Centre des Affaires des Lilas, 77 Avenue des Lilas, 64000 Pau, France	EU/2/99/011	1.3.2023

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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