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 2022 to 28 February 2022

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council [1])

(2022/C 144/01)

[1] OJ L 136, 30.4.2004, p. 1.

— **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
14.2.2022	Apexxnar	pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1612	Suspension for injection	J07AL02	15.2.2022
14.2.2022	Ngenla	somatrogon	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1617	Solution for injection	Pending	15.2.2022
14.2.2022	OKEDI	risperidone	Laboratorios Farmacéuticos Rovi, S.A. Julián Camarillo 35, 28037 Madrid, España	EU/1/21/1621	Powder and solvent for prolonged-release suspension for injection	N05AX08	15.2.2022
14.2.2022	Oxbryta	voxelotor	Global Blood Therapeutics Netherlands B.V. Strawinskylaan 3051, 1077 ZX Amsterdam, Noord-Holland, Nederland	EU/1/21/1622	Film-coated tablet	B06AX	15.2.2022
14.2.2022	Saphnelo	anifrolumab	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1623	Concentrate for solution for infusion	L04AA51	15.2.2022
16.2.2022	Kerendia	finerenone	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/21/1616	Film-coated tablet	C03DA05	17.2.2022
16.2.2022	Sapropterin Dipharma	sapropterin	Dipharma B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	EU/1/21/1620	Powder for oral solution Soluble tablet	A16AX07	17.2.2022

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
16.2.2022	Sitagliptin/Metformin hydrochloride Mylan	sitagliptin/metformin hydrochloride	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1619	Film-coated tablet	A10BD07	21.2.2022
16.2.2022	Tepmetko	tepotinib	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/21/1596	Film-coated tablet	L01EX21	17.2.2022
21.2.2022	Ontilyv	opicapone	Bial — Portela & C[a], SA À Av. da Siderurgia Nacional, 4745-457 S. Mamede do Coronado, Portugal	EU/1/21/1578	Capsule, hard	N04BX04	22.2.2022

— **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
2.2.2022	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	2.2.2022
3.2.2022	Clopidogrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	7.2.2022
3.2.2022	DaTSCAN	GE Healthcare B.V. De Rondom 8, 5612 AP, Eindhoven, Nederland	EU/1/00/135	9.2.2022
3.2.2022	Edarbi	Takeda Pharma A/S Delta Park 45, 2665 Vallensbæk Strand, Danmark	EU/1/11/734	8.2.2022
3.2.2022	Efavirenz/Emtricitabine/Tenofovir disoproxil Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1263	9.2.2022
3.2.2022	Nyxoid	Mundipharma Corporation (Ireland) Limited Millbank House, Arkle Road, Sandyford Industrial Estate, Dublin 18, Ireland	EU/1/17/1238	7.2.2022
3.2.2022	Pregabalin Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1021	8.2.2022
3.2.2022	Vivanza	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/249	7.2.2022
3.2.2022	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	4.2.2022
3.2.2022	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	4.2.2022
4.2.2022	Cialis	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/02/237	8.2.2022
4.2.2022	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	4.2.2022
4.2.2022	Ebixa	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/02/219	8.2.2022
4.2.2022	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	7.2.2022
4.2.2022	Entacapone Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/665	8.2.2022
4.2.2022	HyQvia	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/13/840	7.2.2022

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4.2.2022	Iressa	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/526	7.2.2022
4.2.2022	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/331	9.2.2022
4.2.2022	Noxafil	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/320	8.2.2022
4.2.2022	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	9.2.2022
4.2.2022	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	7.2.2022
4.2.2022	Roclanda	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/20/1502	10.2.2022
4.2.2022	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	8.2.2022
4.2.2022	Temozolomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/10/615	9.2.2022
4.2.2022	Vantobra	PARI Pharma GmbH Moosstraße 3, 82319 Starnberg, Deutschland	EU/1/18/1350	10.2.2022
4.2.2022	Yellox	BAUSCH + LOMB IRELAND LIMITED 3013 Lake Drive Citywest Business Campus Dublin 24, D24PPT3, Ireland	EU/1/11/692	14.2.2022
4.2.2022	Zoledronic acid Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/12/800	7.2.2022
10.2.2022	Ameluz	Biofrontera Bioscience GmbH Hemmelrather Weg 201, 51377 Leverkusen, Deutschland	EU/1/11/740	15.2.2022
10.2.2022	Axumin	Blue Earth Diagnostics Ireland Ltd 6th Floor, 2 Grand Canal Square, Dublin 2, Ireland	EU/1/17/1186	15.2.2022
10.2.2022	Cotellic	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/15/1048	14.2.2022
10.2.2022	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/18/1290	15.2.2022

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10.2.2022	Wakix	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/15/1068	3.3.2022
14.2.2022	Cubicin	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/328	18.2.2022
14.2.2022	Incruse Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/922	4.3.2022
14.2.2022	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	15.2.2022
14.2.2022	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	16.2.2022
14.2.2022	Waylivra	Akcea Therapeutics Ireland Limited Regus House, Harcourt Centre, Harcourt Road, Dublin 2, Ireland	EU/1/19/1360	21.2.2022
14.2.2022	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	17.2.2022
16.2.2022	AMGLIDIA	AMMTeK 55 rue de Turbigo, 75003 Paris, France	EU/1/18/1279	16.2.2022
16.2.2022	Besponsa	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/17/1200	17.2.2022
16.2.2022	CellCept	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/96/005	17.2.2022
16.2.2022	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	17.2.2022
16.2.2022	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	17.2.2022
16.2.2022	ellaOne	Laboratoire HRA Pharma 200 avenue de Paris, 92320 Chatillon, France	EU/1/09/522	23.2.2022
16.2.2022	Envarsus	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/935	21.2.2022
16.2.2022	Febuxostat Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	17.2.2022

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16.2.2022	JEMPERLI	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	17.2.2022
16.2.2022	Laventair Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/899	4.3.2022
16.2.2022	Mayzent	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1414	17.2.2022
16.2.2022	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/09/523	17.2.2022
16.2.2022	Myclausen	Passauer Pharma GmbH Eiderstedter Weg 3, 14129 Berlin, Deutschland	EU/1/10/647	17.2.2022
16.2.2022	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	21.2.2022
16.2.2022	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	21.2.2022
16.2.2022	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	17.2.2022
16.2.2022	Temybric Ellipta	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/19/1378	4.3.2022
16.2.2022	Yuflyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/20/1513	2.3.2022
16.2.2022	Zykadia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/15/999	17.2.2022
17.2.2022	Advagraf	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/07/387	21.2.2022
17.2.2022	Avonex	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/97/033	23.2.2022
17.2.2022	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	18.2.2022
17.2.2022	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	21.2.2022
17.2.2022	Nexium Control	GlaxoSmithKline Dungarvan Limited Dungarvan, Co. Waterford, Ireland	EU/1/13/860	24.2.2022

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18.2.2022	Tarceva	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/05/311	21.2.2022
18.2.2022	Zelboraf	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/12/751	21.2.2022
21.2.2022	Clopidogrel Taw Pharma	Taw Pharma (Ireland) Limited 104 Lower Baggot Street, Dublin 2, Ireland	EU/1/09/559	22.2.2022
21.2.2022	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	25.2.2022
21.2.2022	Ogivri	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1341	23.2.2022
21.2.2022	Refixia	Novo Nordisk A/S Novo Allé, 2880 Bagsværd, Danmark	EU/1/17/1193	24.2.2022
21.2.2022	Skilarence	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/17/1201	23.2.2022
23.2.2022	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	25.2.2022
24.2.2022	ADVATE	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/03/271	28.2.2022
24.2.2022	Bortezomib Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/16/1114	25.2.2022
24.2.2022	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	25.2.2022
24.2.2022	Irbesartan Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/576	28.2.2022
24.2.2022	JEVTANA	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/11/676	28.2.2022
24.2.2022	Lacosamide UCB	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1383	25.2.2022
24.2.2022	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	25.2.2022

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24.2.2022	Senshio	Shionogi B.V. Kingsfordweg 151, 1043 GR Amsterdam, Nederland	EU/1/14/978	25.2.2022
28.2.2022	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	28.2.2022
28.2.2022	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	2.3.2022
28.2.2022	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	1.3.2022
28.2.2022	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	2.3.2022
28.2.2022	Xagrid	Takeda Pharmaceuticals International AG Ireland Branch 50-58 Baggot Street Lower, Block 3 Miesian Plaza, Dublin 2, Co Dublin, D02 Y754, Ireland	EU/1/04/295	1.3.2022

— **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
3.2.2022	Vivanza	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/249	7.2.2022

— **Modification of a marketing authorisation** (Article 38 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
1.2.2022	Bravecto	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/13/158	3.2.2022
1.2.2022	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	2.2.2022
8.2.2022	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	9.2.2022
8.2.2022	Zulvac 8 Ovis	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/09/104	9.2.2022

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
10.2.2022	Draxxin	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/03/041	16.2.2022
10.2.2022	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/98/006	14.2.2022
10.2.2022	Onsior	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/08/089	11.2.2022
28.2.2022	Innovax-ND-IBD	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/213	2.3.2022
28.2.2022	Innovax-ND-ILT	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/20/256	2.3.2022

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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