C/2024/2197

27.3.2024

Sommarju ta' deċiżjonijiet tal-Unjoni Ewropea dwar l-awtorizzazzjonijiet għat-tqegħid fis-suq tal-prodotti mediċinali mill-1 ta' Frar 2024 sad-29 ta' Frar 2024

(Ippubblikat skont l-Artikolu 13 jew l-Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill [1] jew l-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill [2])

(C/2024/2197)

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

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	INN (Denominazzjoni Internazzjonali Komuni)	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Forma farmaċewtika	Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku)	Data ta' notifika
9.2.2024	Casgevy	exagamglogene autotemcel	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/23/1787	Dispersjoni għal infużjoni	B06AX	12.2.2024
9.2.2024	Mevlyq	eribulina	YES Pharmaceutical Development Services GmbH Basler Strasse 7, 61352 Bad Homburg, Deutschland	EU/1/23/1789	Soluzzjoni għall-injezzjoni	L01XX41	13.2.2024
9.2.2024	Skyclarys	omaveloxolone	Reata Ireland Limited Block A, George's Quay Plaza, George's Quay, Dublin 2, D02 E440, Ireland	EU/1/23/1786	Kapsula, iebsa	Pending	12.2.2024
16.2.2024	Ibuprofen Gen.Orph	ibuprofen	Gen.Orph 185 Bureaux de la Colline, 92213 Saint Cloud Cedex, France	EU/1/23/1791	Soluzzjoni għall-injezzjoni	C01EB16	21.2.2024
16.2.2024	Pomalidomide Viatris	pomalidomide	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1785	Kapsula, iebsa	L04AX06	19.2.2024
16.2.2024	Velsipity	etrasimod	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1790	Pillola miksija b'rita	L04AE05	19.2.2024
19.2.2024	Dabigatran etexilate Leon Farma	dabigatran etexilate	Laboratorios Leon Farma S.A. C/ La Vallina s/n, Poligono Industrial Navatejera, 24193 Villaquilambre León, España	EU/1/23/1769	Kapsula, iebsa	B01AE07	21.2.2024

Data tad-deċiżjoni	Isem tal-prodott mediċinali	INN (Denominazzjoni Internazzjonali Komuni)	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Forma farmaċewtika	Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku)	Data ta' notifika
22.2.2024	Holoclar	Ċelluli awtologi tal-epitelju tal-kornea umana mkabbra ex vivo li fihom ċelluli staminali	Holostem S.r.l. Via Glauco Gottardi 100, 41125 Modena, Italia	EU/1/14/987	Ekwivalenti għal tessut ħaj	S01XA19	23.2.2024

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
1.2.2024	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	5.2.2024
1.2.2024	Hexacima	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/13/828	5.2.2024
1.2.2024	Hexyon	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/13/829	2.2.2024
1.2.2024	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	3.2.2024
1.2.2024	Mirvaso	Galderma International Tour Europlaza, 20 avenue André Prothin, La Défense 4, La Défense Cedex 92927, France	EU/1/13/904	6.2.2024
1.2.2024	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/08/448	5.2.2024
1.2.2024	Simponi	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/09/546	6.2.2024
1.2.2024	Tafinlar	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/865	2.2.2024
1.2.2024	Thiotepa Riemser	Esteve Pharmaceuticals GmbH Hohenzollerndamm 150-151, 14199 Berlin, Deutschland	EU/1/21/1536	5.2.2024
1.2.2024	Tybost	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/872	5.2.2024
6.2.2024	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	7.2.2024
6.2.2024	Cegfila	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/19/1409	7.2.2024
6.2.2024	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1040	8.2.2024
6.2.2024	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	7.2.2024
6.2.2024	Nyxoid	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/17/1238	7.2.2024
6.2.2024	Sixmo	L. Molteni & C. dei F.lli Alitti Società di .Esercizio .S.p.A Strada Statale 67, Loc. Granatieri, 50018 Scandicci (Firenze), Italia	EU/1/19/1369	7.2.2024

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
6.2.2024	SomaKit TOC	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/16/1141	8.2.2024
8.2.2024	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	9.2.2024
8.2.2024	Coagadex	BPL Bioproducts Laboratory GmbH Dornhofstrasse 34, 63263 Neu-Isenburg, Deutschland	EU/1/16/1087	12.2.2024
8.2.2024	Dynastat	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/209	9.2.2024
8.2.2024	QINLOCK	Deciphera Pharmaceuticals (Netherlands) B.V. Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland	EU/1/21/1569	12.2.2024
8.2.2024	Scintimun	CIS bio international Boîte Postale 32, 91192 Gif-sur-Yvette, France	EU/1/09/602	9.2.2024
8.2.2024	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	9.2.2024
8.2.2024	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	9.2.2024
8.2.2024	Zypadhera	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/08/479	9.2.2024
8.2.2024	Zyprexa	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/96/022	9.2.2024
8.2.2024	Zyprexa Velotab	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/99/125	9.2.2024
9.2.2024	Clopidogrel Krka d. d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	12.2.2024
9.2.2024	Doptelet	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/19/1373	14.2.2024
9.2.2024	DuoPlavin	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/10/619	12.2.2024
9.2.2024	Esperoct	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/19/1374	12.2.2024
9.2.2024	Protopic	Leo Pharma A/S Industriparken 55, 2750 Ballerup, Danmark	EU/1/02/201	13.2.2024
9.2.2024	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	12.2.2024
9.2.2024	Translarna	PTC Therapeutics International Limited 5th Floor, 3 Grand Canal Plaza, Grand Canal Street Upper, Dublin 4, D04 EE70, Ireland	EU/1/13/902	12.2.2024
9.2.2024	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	15.2.2024

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
16.2.2024	Arixtra	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/02/206	19.2.2024
16.2.2024	Azopt	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/00/129	19.2.2024
16.2.2024	Baqsimi	Amphastar France Pharmaceuticals Usine Saint Charles, Eragny Sur Epte, 60590 France	EU/1/19/1406	20.2.2024
16.2.2024	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	19.2.2024
16.2.2024	Bylvay	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/21/1566	19.2.2024
16.2.2024	Cayston	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/09/543	19.2.2024
16.2.2024	Entyvio	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/14/923	19.2.2024
16.2.2024	Evoltra	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/334	19.2.2024
16.2.2024	Fetcroja	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/20/1434	19.2.2024
16.2.2024	Hemlibra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/18/1271	20.2.2024
16.2.2024	Herzuma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/17/1257	19.2.2024
16.2.2024	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	19.2.2024
16.2.2024	IMJUDO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1713	19.2.2024
16.2.2024	Imraldi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/17/1216	21.2.2024
16.2.2024	Jylamvo	Therakind (Europe) Limited Paramount Court, Corrig Road, Sandyford Business Park, Dublin 18, D18 R9C7, Ireland	EU/1/17/1172	27.2.2024
16.2.2024	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/20/1468	19.2.2024
16.2.2024	Lupkynis	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	20.2.2024

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
16.2.2024	LysaKare	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/19/1381	19.2.2024
16.2.2024	Natpar	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1078	19.2.2024
16.2.2024	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	21.2.2024
16.2.2024	Pregabalin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/15/1027	19.2.2024
16.2.2024	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	19.2.2024
16.2.2024	Senshio	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/14/978	19.2.2024
16.2.2024	Stayveer	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/832	19.2.2024
16.2.2024	Stocrin	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/99/111	19.2.2024
16.2.2024	Truvada	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/04/305	19.2.2024
16.2.2024	Viread	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/01/200	19.2.2024
16.2.2024	Vydura	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1645	19.2.2024
16.2.2024	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	19.2.2024
22.2.2024	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	27.2.2024
22.2.2024	Docetaxel Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/769	26.2.2024
22.2.2024	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	26.2.2024
22.2.2024	Pravafenix	LABORATOIRES SMB SA 26-28 rue de la Pastorale / 26-28 Herderslieds-traat, 1080 Brussel/Bruxelles, Belgique/België	EU/1/11/679	23.2.2024
22.2.2024	Skytrofa	Ascendis Pharma Endocrinology Division A/S Tuborg Boulevard 12, 2900 Hellerup, Danmark	EU/1/21/1607	23.2.2024

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
22.2.2024	Spectrila	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/15/1072	26.2.2024
22.2.2024	Strensiq	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1015	26.2.2024
22.2.2024	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	23.2.2024
23.2.2024	BLENREP	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/20/1474	29.2.2024
26.2.2024	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	28.2.2024
29.2.2024	Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/12/802	1.3.2024
29.2.2024	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	1.3.2024
29.2.2024	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	1.3.2024
29.2.2024	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/08/445	4.3.2024
29.2.2024	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	1.3.2024

— **Irtirar ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill)

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
1.2.2024	Sustiva	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/99/110	3.2.2024
9.2.2024	Apealea	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/18/1292	14.2.2024

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill; L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
1.2.2024	Solensia	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	2.2.2024
1.2.2024	Solensia	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	2.2.2024

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
1.2.2024	Zactran	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/08/082	6.2.2024
29.2.2024	Metacam	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/97/004	1.3.2024
29.2.2024	REXXOLIDE	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/20/263	6.3.2024

Kull min jixtieq jikkonsulta r-rapport ta' evalwazzjoni pubblika dwar il-prodotti mediċinali kkonċernati u d-deċiżjonijiet marbuta magħhom għandu jikkuntattja lil:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS