C/2024/2197

27.3.2024.

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. veljače 2024. do 29. veljače 2024.

(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća [1] ili člankom 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća [2])

(C/2024/2197)

[1] SL L 136, 30.4.2004., str. 1.
[2] SL L 4, 7.1.2019., str. 43.

— **Izdavanje odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
9.2.2024.	Casgevy	eksagamglogen autotemcel	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/23/1787	Disperzija za infuziju	B06AX	12.2.2024.
9.2.2024.	Mevlyq	eribulin	YES Pharmaceutical Development Services GmbH Basler Strasse 7, 61352 Bad Homburg, Deutschland	EU/1/23/1789	Otopina za injekciju	L01XX41	13.2.2024.
9.2.2024.	Skyclarys	omaveloksolon	Reata Ireland Limited Block A, George's Quay Plaza, George's Quay, Dublin 2, D02 E440, Ireland	EU/1/23/1786	Kapsula, tvrda	Pending	12.2.2024.
16.2.2024.	Ibuprofen Gen.Orph	ibuprofena	Gen.Orph 185 Bureaux de la Colline, 92213 Saint Cloud Cedex, France	EU/1/23/1791	Otopina za injekciju	C01EB16	21.2.2024.
16.2.2024.	Pomalidomide Viatris	pomalidomid	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1785	Kapsula, tvrda	L04AX06	19.2.2024.
16.2.2024.	Velsipity	Etrasimoda	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1790	Filmom obložena tableta	L04AE05	19.2.2024.
19.2.2024.	Dabigatran etexilate Leon Farma	dabigatraneteksilat	Laboratorios Leon Farma S.A. C/ La Vallina s/n, Poligono Industrial Navatejera, 24193 Villaquilambre León, España	EU/1/23/1769	Kapsula, tvrda	B01AE07	21.2.2024.

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
22.2.2024.	Holoclar	Ex vivo uzgojene autologne epitelne stanice ljudske rožnice koje sadrže matične stanice	Holostem S.r.l. Via Glauco Gottardi 100, 41125 Modena, Italia	EU/1/14/987	Ekvivalent živoga tkiva	S01XA19	23.2.2024.

— **Izmjena odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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 Herdersliedstraat, 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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

— **Povlačenje odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

— **Izmjena odobrenja za stavljanje u promet** (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća; članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS