IV.

(Obavijesti)

OBAVIJESTI INSTITUCIJA, TIJELA, UREDA I AGENCIJA EUROPSKE UNIJE

EUROPSKA KOMISIJA

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. veljače 2023. do 28. veljače 2023.

(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])

(2023/C 118/01)

[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
15.2.2023.	Dimethyl Fumarate Accord	dimetilfumarat	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1711	Želučanootporna tvrda kapsula	L04AX07	17.2.2023.
20.2.2023.	Hemgenix	etranakogen dezaparvovek	CSL Behring GmbH D-35041 Marburg, Deutschland	EU/1/22/1715	Koncentrat za otopinu za infuziju	B06	23.2.2023.
20.2.2023.	IMJUDO	tremelimumab	AstraZeneca AB Forskargatan 18, 151 85 Södertälje, Sverige	EU/1/22/1713	Koncentrat za otopinu za infuziju	L01FX20	23.2.2023.
20.2.2023.	Tremelimumab AstraZeneca	tremelimumab	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1712	Koncentrat za otopinu za infuziju	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	Filmom obložena tableta	J05AE30	27.2.2023.

— **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
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.

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

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

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

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

— **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
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.

— **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
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.

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
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NETHERLANDS