C/2023/298

31.10.2023.

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. rujna 2023. do 30. rujna 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])

(C/2023/298)

[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
15.9.2023.	Apretude	kabotegravir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	Filmom obložena tableta Suspenzija s produljenim oslobađanjem za injekciju	J05AJ04	20.9.2023.
15.9.2023.	Enrylaze	krizantaspaze	Jazz Pharmaceuticals Ireland Limited 5th Floor, Waterloo Exchange, Waterloo Road, Dublin 4, D04 E5W7, Ireland	EU/1/23/1747	otopina za injekciju ili infuziju	L01XX02	21.9.2023.
15.9.2023.	Inaqovi	decitabin / cedazuridin	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/23/1756	Filmom obložena tableta	L01BC58	18.9.2023.
15.9.2023.	Litfulo	ritlecitinib	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1755	Kapsula, tvrda	L04AF08	18.9.2023.
15.9.2023.	Lyfnua	gefapiksant	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1613	Filmom obložena tableta	R05DB29	20.9.2023.
15.9.2023.	ORSERDU	elacestranta	Stemline Therapeutics B.V. Basisweg 10, 1043 AP, Amsterdam, Noord--Holland, Nederland	EU/1/23/1757	Filmom obložena tableta	L02BA04	18.9.2023.
15.9.2023.	Tevimbra	tislelizumab	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1758	Koncentrat za otopinu za infuziju	L01FF09	19.9.2023.
15.9.2023.	Tyenne	tocilizumab	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/23/1754	Koncentrat za otopinu za infuziju Otopina za injekciju	L04AC07	18.9.2023.
15.9.2023.	Yesafili	aflibercept	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1751	Otopina za injekciju (injekcija)	S01LA05	19.9.2023.
22.9.2023.	Tepkinly	epkoritamab	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	Otopina za injekciju	Pending	25.9.2023.

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
22.9.2023.	Tyruko	natalizumaba	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/23/1745	Koncentrat za otopinu za infuziju	L04AA23	25.9.2023.
29.9.2023.	Degarelix Accord	degareliksacetat	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/23/1753	Prašak i otapalo za otopinu za injekciju	L02BX02	3.10.2023.

— **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
1.9.2023.	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	4.9.2023.
1.9.2023.	Adtralza	Leo Pharma A/S Industriparken 55, 2750 Ballerup, Danmark	EU/1/21/1554	7.9.2023.
1.9.2023.	Emgality	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1330	4.9.2023.
1.9.2023.	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	4.9.2023.
1.9.2023.	Poteligeo	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/18/1335	19.9.2023.
11.9.2023.	Apealea	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/18/1292	12.9.2023.
11.9.2023.	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	12.9.2023.
11.9.2023.	Fulphila	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1329	12.9.2023.
11.9.2023.	GHRYVELIN	Atnahs Pharma Netherlands B.V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark	EU/1/18/1337	15.9.2023.
11.9.2023.	Imlygic	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1064	13.9.2023.
11.9.2023.	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030	12.9.2023.
11.9.2023.	Irbesartan Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/06/376	14.9.2023.
11.9.2023.	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	12.9.2023.
11.9.2023.	Lumeblue	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/20/1470	12.9.2023.
11.9.2023.	OKEDI	Laboratorios Farmacéuticos Rovi, S.A. Julián Camarillo 35, 28037 Madrid, España	EU/1/21/1621	12.9.2023.
11.9.2023.	Opatanol	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/02/217	12.9.2023.
11.9.2023.	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	12.9.2023.
11.9.2023.	Vimizim	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/14/914	12.9.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.9.2023.	Fulphila	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1329	14.9.2023.
15.9.2023.	Afinitor	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/538	18.9.2023.
15.9.2023.	Amlodipin/Valsartan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1092	18.9.2023.
15.9.2023.	Bevespi Aerosphere	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1339	22.9.2023.
15.9.2023.	Celsentri	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/07/418	21.9.2023.
15.9.2023.	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	18.9.2023.
15.9.2023.	Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1222	18.9.2023.
15.9.2023.	Esperoct	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/19/1374	21.9.2023.
15.9.2023.	Fortacin	Recordati Ireland Ltd Raheens East, Ringaskiddy Co. Cork P43 KD30, Ireland	EU/1/13/881	21.9.2023.
15.9.2023.	GAVRETO	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	18.9.2023.
15.9.2023.	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	18.9.2023.
15.9.2023.	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/11/687	21.9.2023.
15.9.2023.	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/945	18.9.2023.
15.9.2023.	Instanyl	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/09/531	22.9.2023.
15.9.2023.	Irbesartan / Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	19.9.2023.
15.9.2023.	Iressa	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/526	18.9.2023.
15.9.2023.	Jinarc	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/15/1000	18.9.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
15.9.2023.	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	18.9.2023.
15.9.2023.	Kinzalkomb	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/02/214	18.9.2023.
15.9.2023.	Kiovig	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/05/329	21.9.2023.
15.9.2023.	Levetiracetam Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/889	18.9.2023.
15.9.2023.	MicardisPlus	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/02/213	21.9.2023.
15.9.2023.	M-M-RVAXPRO	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/06/337	18.9.2023.
15.9.2023.	Olumiant	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	18.9.2023.
15.9.2023.	Orgovyx	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1642	18.9.2023.
15.9.2023.	Pregabalin Sandoz GmbH	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1012	18.9.2023.
15.9.2023.	Prolia	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/10/618	18.9.2023.
15.9.2023.	Remsima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/13/853	18.9.2023.
15.9.2023.	Sitagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1661	18.9.2023.
15.9.2023.	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	18.9.2023.
15.9.2023.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España	EU/1/20/1507	15.9.2023.
15.9.2023.	Sugammadex Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1583	19.9.2023.
15.9.2023.	Tecfidera	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/13/837	19.9.2023.
15.9.2023.	Tenkasi	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/989	18.9.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
15.9.2023.	Tezspire	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1677	18.9.2023.
15.9.2023.	Toviaz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/386	18.9.2023.
15.9.2023.	Tygacil	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/336	18.9.2023.
15.9.2023.	Vantobra	PARI Pharma GmbH Moosstraße 3, 82319 Starnberg, Deutschland	EU/1/18/1350	19.9.2023.
15.9.2023.	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	18.9.2023.
15.9.2023.	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	26.9.2023.
15.9.2023.	Vyvgart	argenx BV Industriepark-Zwijnaarde 7, 9052 Gent, België	EU/1/22/1674	20.9.2023.
15.9.2023.	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	18.9.2023.
15.9.2023.	Zytiga	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/11/714	18.9.2023.
18.9.2023.	Rydapt	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1218	20.9.2023.
22.9.2023.	Ciambra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/1055	25.9.2023.
22.9.2023.	Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	25.9.2023.
22.9.2023.	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	25.9.2023.
22.9.2023.	Imcivree	Rhythm Pharmaceuticals Netherlands B.V. Radarweg 29, 1043 NX Amsterdam, Nederland	EU/1/21/1564	26.9.2023.
22.9.2023.	Imvanex	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/13/855	5.10.2023.
22.9.2023.	Kesimpta	Novartis Ireland Limited Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland	EU/1/21/1532	3.10.2023.
22.9.2023.	Myozyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/333	28.9.2023.
22.9.2023.	Ranivisio	Midas Pharma GmbH Rheinstraße 49, D-55218 Ingelheim, Deutschland	EU/1/22/1673	25.9.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.9.2023.	Sunosi	Atnahs Pharma Netherlands B. V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Denmark	EU/1/19/1408	25.9.2023.
22.9.2023.	TAVLESSE	Instituto Grifols, S.A. Can Guasc, 2, Parets del Vallès, 08150 Barcelona, España	EU/1/19/1405	27.9.2023.
22.9.2023.	Vaxchora	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/20/1423	25.9.2023.
22.9.2023.	Vildagliptin/metforminklorid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/21/1611	26.9.2023.

— **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
11.9.2023.	Lenalidomide Krka d.d. Novo mesto	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/20/1520	14.9.2023.
11.9.2023.	Pandemic influenza vaccine H5N1 BAXTER	Resilience Biomanufacturing Ireland Limited 2 Shelbourne Buildings, Crampton Avenue, Dublin 4, D04 W3V6, Ireland	EU/1/09/571	15.9.2023.

— **Izdavanje 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	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
11.9.2023.	YURVAC RHD	Hemoragijska bolest kunića i cjepivo RHDV2 (rekombinantno)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/23/298	Emulzija za injekciju	QI08AV	12.9.2023.

— **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
11.9.2023.	Apoquel	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	12.9.2023.
11.9.2023.	Prolevare	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/23/295	12.9.2023.

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
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS