Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. kolovoza 2024. do 31. kolovoza 2024.

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

(C/2024/5667)

— **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
1.8.2024	ADZYNMA	rADAMTS13	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/24/1837	Prašak i otapalo za otopinu za injekciju	B01AD13	2.8.2024
1.8.2024	GalliaPharm	germanijev[^{68}Ge] klorid / galijev[^{68}Ga] klorid	Eckert & Ziegler Radiopharma GmbH Robert-Rössle-Straße 10, 13125 Berlin, Deutschland	EU/1/24/1836	Generator radionuklida.	V09X	2.8.2024
22.8.2024	AKANTIOR	poliheksanid	SIFI S.p.A. Via Ercole Patti 36, 95025 Aci Sant'Antonio (CT), Italia	EU/1/24/1840	Kapi za oko, otopina	S01AX24	23.8.2024
22.8.2024	Balversa	erdafitinib	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1841	Filmom obložena tableta	L01EN01	23.8.2024
22.8.2024	Enzalutamide Viatris	enzalutamid	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/24/1842	Filmom obložena tableta	L02BB04	23.8.2024
22.8.2024	EURneffy	epinefrin	ARS Pharmaceuticals IRL, Limited The Black Church, Saint Mary's Place North, Dublin 7, Co. Dublin, D07 P4AX, Ireland	EU/1/24/1846	sprej za nos, otopina	C01CA24	23.8.2024
22.8.2024	mRESVIA	Jednolančana glasnička RNA (mRNA) s kapom na 5'-kraju koja kodira glikoprotein F respiratornog sincicijskog	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/24/1849	Disperzija za injekciju	J07BX05	23.8.2024

([1]) SL L 136, 30.4.2004, str. 1, ELI: https://data.europa.eu/eli/reg/2004/726/oj.
([2]) SL L 4, 7.1.2019, str. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

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
		virusa stabiliziran u prefuzijskoj konformaciji					
22.8.2024	Nilotinib Accord	nilotinib	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1845	Kapsula, tvrda	L01EA03	23.8.2024
22.8.2024	Ordspono	odronekstamab	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/24/1843	Otopina za infuziju	Pending	23.8.2024
22.8.2024	Piasky	Krovalimab	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/24/1848	otopina za injekciju ili infuziju	L04AJ07	26.8.2024
22.8.2024	STEQEYMA	ustekinumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1844	Koncentrat za otopinu za infuziju Otopina za injekciju u napunjenoj štrcaljki	L04AC05	23.8.2024
22.8.2024	Tauvid	flortaucipir (18F)	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/24/1799	Otopina za injekciju	V09AX07	26.8.2024
22.8.2024	Winrevair	sotatercept	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/24/1850	Prašak i otapalo za otopinu za injekciju Prašak za otopinu za injekciju	C02KX06	27.8.2024

ELI: http://data.europa.eu/eli/C/2024/5667/oj

— **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
1.8.2024	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118	6.8.2024
1.8.2024	Beyfortus	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/22/1689	2.8.2024
1.8.2024	Bimzelx	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/21/1575	5.8.2024
1.8.2024	Edistride	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1052	2.8.2024
1.8.2024	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	6.8.2024
1.8.2024	Noxafil	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/320	2.8.2024
1.8.2024	Reagila	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/17/1209	15.8.2024
1.8.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	5.8.2024
1.8.2024	Vosevi	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/17/1223	6.8.2024
5.8.2024	ADVATE	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/03/271	6.8.2024
5.8.2024	CAMZYOS	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1716	6.8.2024
5.8.2024	Dabigatran Etexilate Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1665	12.8.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
5.8.2024	Dapagliflozin Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1721	6.8.2024
5.8.2024	Filsuvez	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/22/1652	8.8.2024
5.8.2024	Fotivda	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1215	13.8.2024
5.8.2024	Lojuxta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/13/851	8.8.2024
5.8.2024	Pegasys	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/02/221	6.8.2024
5.8.2024	Skyclarys	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/23/1786	6.8.2024
5.8.2024	Vyndaqel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/11/717	6.8.2024
9.8.2024	Actos	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/00/150	21.8.2024
9.8.2024	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	12.8.2024
9.8.2024	Xarelto	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/08/472	12.8.2024
12.8.2024	Hefiya	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1287	13.8.2024
12.8.2024	Lynparza	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/14/959	13.8.2024
12.8.2024	TRIXEO AEROSPHERE	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1498	13.8.2024
12.8.2024	Zypadhera	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/08/479	14.8.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.8.2024	Abrysvo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1752	19.8.2024
16.8.2024	Competact	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/06/354	9.9.2024
16.8.2024	Jaypirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/23/1738	19.8.2024
16.8.2024	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	19.8.2024
16.8.2024	Roctavian	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/22/1668	22.8.2024
16.8.2024	Spinraza	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/17/1188	19.8.2024
16.8.2024	Tepkinly	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	19.8.2024
22.8.2024	Baqsimi	Amphastar France Pharmaceuticals Usine Saint Charles, Eragny Sur Epte, 60590 France	EU/1/19/1406	23.8.2024
22.8.2024	Betmiga	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/12/809	27.8.2024
22.8.2024	Cegfila	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/19/1409	23.8.2024
22.8.2024	Clopidogrel/Acetylsalicylic acid Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	23.8.2024
22.8.2024	Copiktra	Secura Bio Limited 32 Molesworth Street, Dublin 2 D02 Y512, Co. Dublin, Ireland	EU/1/21/1542	29.8.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.8.2024	Cresemba	Basilea Pharmaceutica Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/15/1036	23.8.2024
22.8.2024	Evenity	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1411	26.8.2024
22.8.2024	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/945	23.8.2024
22.8.2024	Instanyl	Istituto Gentili S.r.l. Via San Giuseppe Cottolengo 15, 20143 Milano, Italia	EU/1/09/531	27.8.2024
22.8.2024	Jylamvo	Oresund Pharma ApS Orient Plads 1, 2150 Nordhavn, Danmark	EU/1/17/1172	23.8.2024
22.8.2024	Jyseleca	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/20/1480	28.8.2024
22.8.2024	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	26.8.2024
22.8.2024	Quofenix	A. Menarini - Industrie Farmaceutiche Riunite - s.r.l. Via Sette Santi 3, 50131 Florence, Italia	EU/1/19/1393	27.8.2024
22.8.2024	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	23.8.2024
22.8.2024	Savene	CNX Therapeutics Ireland Limited 5th Floor Rear, Connaught House, 1 Burlington Road, Dublin 4, Ireland	EU/1/06/350	23.8.2024
22.8.2024	Signifor	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/12/753	26.8.2024
22.8.2024	Spravato	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	23.8.2024
22.8.2024	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	23.8.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.8.2024	XALKORI	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/793	23.8.2024
26.8.2024	Arexvy	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/23/1740	27.8.2024
26.8.2024	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	27.8.2024
26.8.2024	Slenyto	RAD Neurim Pharmaceuticals EEC SARL 4 rue de Marivaux, 75002 Paris, France	EU/1/18/1318	28.8.2024
26.8.2024	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	27.8.2024
29.8.2024	Abiraterone Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1512	30.8.2024
29.8.2024	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	3.9.2024
29.8.2024	Ilaris	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/564	30.8.2024
29.8.2024	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	30.8.2024
29.8.2024	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	3.9.2024
29.8.2024	Opfolda	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/23/1737	30.8.2024
29.8.2024	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	30.8.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
29.8.2024	Vyvgart	argenx BV Industriepark-Zwijnaarde 7, 9052 Gent, België	EU/1/22/1674	30.8.2024
29.8.2024	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	30.8.2024
30.8.2024	ADYNOVI	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/17/1247	3.9.2024
30.8.2024	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	2.9.2024
30.8.2024	Nordimet	Nordic Group B.V. Siriusdreef 41, 2132 WT Hoofddorp, Nederland	EU/1/16/1124	2.9.2024
30.8.2024	Riltrava Aerosphere	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1604	2.9.2024

— **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
2.8.2024	NYXTHRACIS	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/20/1485	5.8.2024

— **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
9.8.2024	DIVENCE IBR Marker Live	Cjepivo protiv herpesa goveda tipa 1 (živ)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/318	liofilizat i otapalo za emulziju za injekciju	QI02AD01	20.8.2024
30.8.2024	Cevac Salmune ETI K	*Salmonella enterica*, subsp. *enterica*, serovar Enteritidis; *Salmonella enterica*, subsp. *enterica*, serovar Typhimurium; i *Salmonella enterica*, subsp. *enterica*, serovar Infantis cjepiva (inaktiviran) za kokoši	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/24/320	Suspenzija za injekciju	QI01AB01	2.9.2024
30.8.2024	Porcilis PCV M Hyo ID	Cjepivo protiv cirkovirusa svinja i svinjske enzootske pneumonije (inaktivirano)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/319	Emulzija za injekciju	QI09AL08	2.9.2024

— **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
2.8.2024	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	6.8.2024
2.8.2024	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	6.8.2024
2.8.2024	Daxocox	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/21/270	5.8.2024
2.8.2024	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	5.8.2024
2.8.2024	PREVEXXION RN +HVT	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/23/302	6.8.2024
2.8.2024	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	6.8.2024
5.8.2024	Neptra	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/246	6.8.2024
5.8.2024	Stronghold Plus	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	9.8.2024
5.8.2024	Vaxxitek HVT + IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/02/032	6.8.2024
9.8.2024	PREVEXXION RN	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/254	12.8.2024
9.8.2024	Suvaxyn PRRS MLV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	12.8.2024
20.8.2024	CircoMax	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/21/281	22.8.2024
20.8.2024	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	21.8.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.8.2024	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	23.8.2024
22.8.2024	FATROVAX RHD	FATRO S.p.A. Via Emilia 285, 40064 Ozzano dell'Emilia (BO), ITALIA	EU/2/21/275	23.8.2024
30.8.2024	Clomicalm	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/98/007	2.9.2024
30.8.2024	Vectormune ND	CEVA-Phylaxia Co. Ltd Szállás u. 5, 1107 Budapest, Magyarország	EU/2/15/188	5.9.2024

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