Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. studenoga 2024. do 30. studenoga 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/2024/7468)

— **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
13.11.2024	Afqlir	aflibercept	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1867	Otopina za injekciju	S01LA05	14.11.2024
13.11.2024	Opuviz	aflibercept	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1865	Otopina za injekciju	S01LA05	18.11.2024
14.11.2024	ELAHERE	mirvetuksimab soravtanzin	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/24/1866	Koncentrat za otopinu za infuziju	L01FX26	15.11.2024
14.11.2024	Penbraya	Konjugirano cjepivo protiv meningokoka grupe A, C, W, Y i cjepivo protiv grupe B (rekombinantno, adsorbirano)	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1871	Prašak i suspenzija za suspenziju za injekciju	J07AH11	15.11.2024
14.11.2024	Pomalidomide Teva	pomalidomid	Graf-Arco-Straße 3, 89079 Ulm, Deutschland Teva GmbH	EU/1/24/1868	Kapsula, tvrda	L04AX06	15.11.2024

([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
15.11.2024	Fluad	Cjepivo protiv influence (površinski antigen) inaktivirano, adjuvantirano	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1878	Suspenzija za injekciju	J07BB02	19.11.2024
15.11.2024	Flucelvax	cjepivo protiv influence (površinski antigen, iz staničnih kultura), inaktivirano	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1879	Suspenzija za injekciju	J07BB02	26.11.2024
18.11.2024	Hympavzi	marstacimab	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1874	Otopina za injekciju	B02BX11	19.11.2024
22.11.2024	Theralugand	lutecijev [^{177}Lu] klorid	Eckert & Ziegler Radiopharma GmbH Robert-Rössle-Straße 10, 13125 Berlin, Deutschland	EU/1/24/1852	Radiofarmaceutski prekursor, otopina	V10X	27.11.2024

ELI: http://data.europa.eu/eli/C/2024/7468/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
4.11.2024	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	5.11.2024
4.11.2024	Farydak	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/15/1023	5.11.2024
4.11.2024	Hulio	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1319	6.11.2024
4.11.2024	Inaqovi	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/23/1756	6.11.2024
4.11.2024	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116	5.11.2024
4.11.2024	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	5.11.2024
4.11.2024	Vipdomet	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/13/843	5.11.2024
13.11.2024	Abevmy	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1515	20.11.2024
13.11.2024	Eladynos	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/22/1706	14.11.2024
13.11.2024	ELREXFIO	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1770	15.11.2024
13.11.2024	MenQuadfi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1483	14.11.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
13.11.2024	Ruxience	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/20/1431	15.11.2024
13.11.2024	TAVLESSE	Instituto Grifols, S.A. Can Guasc, 2, Parets del Vallès, 08150 Barcelona, España	EU/1/19/1405	18.11.2024
13.11.2024	Vaxelis	MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, Nederland	EU/1/15/1079	14.11.2024
13.11.2024	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	14.11.2024
14.11.2024	Fingolimod Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1573	15.11.2024
14.11.2024	Fulphila	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1329	27.11.2024
14.11.2024	Givlaari	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/20/1428	19.11.2024
14.11.2024	Incruse Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/922	15.11.2024
14.11.2024	KIMMTRAK	Immunocore Ireland Limited Unit 1 Sky Business Centres, Unit 21 Block Port Tunnel Business Park, Clonshaugh, Dublin 17, Dublin, D17 FY82, Ireland	EU/1/22/1630	18.11.2024
14.11.2024	Laventair Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/899	15.11.2024
14.11.2024	Lenalidomide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/20/1490	15.11.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
14.11.2024	Lumeblue	Cosmo Technologies Ltd Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/20/1470	15.11.2024
14.11.2024	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	15.11.2024
14.11.2024	Rolufta Ellipta	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/17/1174	15.11.2024
14.11.2024	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	15.11.2024
14.11.2024	Sugammadex Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/21/1583	15.11.2024
14.11.2024	Tarceva	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/05/311	20.11.2024
14.11.2024	Tecovirimat SIGA	SIGA Technologies Netherlands B.V. Prinsenhil 29, Breda 4825 AX, Nederland	EU/1/21/1600	19.11.2024
14.11.2024	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	15.11.2024
14.11.2024	Yescarta	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/18/1299	15.11.2024
18.11.2024	Akynzeo	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	19.11.2024
18.11.2024	Apixaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1458	19.11.2024
18.11.2024	Cosentyx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/980	19.11.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
18.11.2024	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	19.11.2024
18.11.2024	Isturisa	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/19/1407	19.11.2024
18.11.2024	Krazati	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1744	19.11.2024
18.11.2024	Lupkynis	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	19.11.2024
18.11.2024	Nevanac	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/433	19.11.2024
18.11.2024	Nilemdo	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1425	27.11.2024
18.11.2024	Nustendi	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1424	27.11.2024
18.11.2024	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	19.11.2024
18.11.2024	Ozawade	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/21/1546	19.11.2024
18.11.2024	Praluent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/15/1031	19.11.2024
18.11.2024	Pylclari	CURIUM PET France Biopole Clermont-Limagne, 3 rue Marie Curie, 63360 Saint-Beauzire, France	EU/1/23/1746	21.11.2024
18.11.2024	Simulect	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/084	19.11.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
18.11.2024	Xolair	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/05/319	19.11.2024
19.11.2024	Victoza	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/09/529	26.11.2024
22.11.2024	Anoro Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/898	25.11.2024
22.11.2024	Beovu	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1417	25.11.2024
22.11.2024	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	26.11.2024
22.11.2024	Bylvay	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/21/1566	29.11.2024
22.11.2024	Cablivi	Ablynx N.V. Technologiepark 21, 9052 Zwijnaarde, België	EU/1/18/1305	25.11.2024
22.11.2024	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	25.11.2024
22.11.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	26.11.2024
22.11.2024	SANCUSO	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/12/766	28.11.2024
22.11.2024	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/15/992	26.11.2024
22.11.2024	Scintimun	CIS bio international Boîte Postale 32, 91192 Gif-sur-Yvette, France	EU/1/09/602	27.11.2024
22.11.2024	Vaxneuvance	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1591	26.11.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.11.2024	Yselty	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/21/1606	25.11.2024
25.11.2024	Hepcludex	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1446	26.11.2024
25.11.2024	Kevzara	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1196	26.11.2024
25.11.2024	Kisqali	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1221	26.11.2024
25.11.2024	Menveo	GSK Vaccines S.r.l. Via Fiorentina 1, 53100 Siena, Italia	EU/1/10/614	26.11.2024
25.11.2024	Orgalutran	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/00/130	27.11.2024
25.11.2024	Supemtek	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1484	28.11.2024
25.11.2024	Tevimbra	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	26.11.2024
25.11.2024	Tigecycline Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1394	26.11.2024
28.11.2024	Azacitidine Betapharm	betapharm Arzneimittel GmbH Kobelweg 95, 86156 Augsburg, Deutschland	EU/1/19/1416	4.12.2024
28.11.2024	Besponsa	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1200	29.11.2024
28.11.2024	Deferasirox Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1412	29.11.2024

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
28.11.2024	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/22/1638	3.12.2024
28.11.2024	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	29.11.2024
29.11.2024	Ameluz	Biofrontera Bioscience GmbH Hemmelrather Weg 201, 51377 Leverkusen, Deutschland	EU/1/11/740	4.12.2024
29.11.2024	Azacitidine Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1426	2.12.2024
29.11.2024	Mircera	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/07/400	3.12.2024
29.11.2024	Tasigna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/422	2.12.2024

— **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
25.11.2024	Extavia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/454	26.11.2024
25.11.2024	PreHevbri	VBI Vaccines B.V. Delflandlaan 1, Queen's Tower Office Number 714, 1062 EA Amsterdam, Nederland	EU/1/22/1641	27.11.2024

— **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
22.11.2024	BRAVECTO TriUNO	Fluralaner / Moksidektin / Pirantel	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/325	Tablete za žvakanje	QP54AB52	28.11.2024
22.11.2024	DuOtic	Betametazon acetat / Terbinafin	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/24/327	Gel za uho	QS02CA90	25.11.2024
22.11.2024	VAXXON ND CLONE	Živo cjepivo protiv newcastleske bolesti	Vaxxinova International B.V Transistorweg 5, 6534 AT Nijmegen,Nederland	EU/2/24/326	liofilizat i otapalo za okulonazalnu suspenziju za piliće	QI01AD06	27.11.2024

— **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
22.11.2024	Bovilis Nasalgen-C	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/23/294	25.11.2024
22.11.2024	Inflacam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/11/134	26.11.2024
22.11.2024	Poulvac Procerta HVT-IBD	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/23/300	26.11.2024
25.11.2024	Eluracat	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/23/297	26.11.2024
25.11.2024	Enteroporc Coli AC	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/262	26.11.2024
25.11.2024	Mometamax Ultra	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/22/289	3.12.2024
25.11.2024	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	28.11.2024
28.11.2024	CLYNAV	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/16/197	29.11.2024

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