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. prosinca 2021. do 31. prosinca 2021.

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

(2022/C 50/01)

([1]) SL L 136, 30.4.2004., str. 1.

— **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
9.12.2021.	Cibinqo	abrocitinib	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	Filmom obložena tableta	D11AH	10.12.2021.
9.12.2021.	Rybrevant	amivantamab	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	Koncentrat za otopinu za infuziju	L01FX18	10.12.2021.
9.12.2021.	Sitagliptin SUN	sitagliptinfumarat	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/21/1598	Filmom obložena tableta	A10BH01	15.12.2021.
13.12.2021.	ASPAVELI	pegcetakoplan	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	Otopina za infuziju	L04AA54	14.12.2021.
13.12.2021.	Vaxneuvance	Cjepivo protiv pneumokoka, polisaharidno, konjugirano (15 valentno), adsorbirano	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1591	Suspenzija za injekciju	J07AL	14.12.2021.
17.12.2021.	Xevudy	sotrovimab	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	Koncentrat za otopinu za infuziju	Pending	17.12.2021.
20.12.2021.	Nuvaxovid	Cjepivo protiv COVID-19 (rekombinantno, adjuvantirano)	Novavax CZ, a.s. Bohumil 138, 281 63 Jevany, Česká republika	EU/1/21/1618	Disperzija za injekciju	J07BX03	20.12.2021.

— **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
2.12.2021.	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	3.12.2021.
2.12.2021.	Ebilfumin	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/14/915	7.12.2021.
2.12.2021.	Ivozall	ORPHELIA Pharma SAS 85 boulevard Saint-Michel, 75005 Pariz, France	EU/1/19/1396	7.12.2021.
2.12.2021.	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	3.12.2021.
2.12.2021.	Revinty Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/929	3.12.2021.
3.12.2021.	Kiovig	Baxter AG Industriestraße 67, 1221 Wien, Österreich	EU/1/05/329	6.12.2021.
3.12.2021.	Lojuxta	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/13/851	15.12.2021.
3.12.2021.	Naglazyme	BioMarin International Limited Shanbally, Ringaskiddy, County Cork P43 R298, Ireland	EU/1/05/324	11.1.2022.
3.12.2021.	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	6.12.2021.
3.12.2021.	Polivy	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/19/1388	7.12.2021.
3.12.2021.	Xagrid	Takeda Pharmaceuticals International AG Ireland Branch 50-58 Baggot Street Lower, Block 3 Miesian Plaza, Dublin 2, Co Dublin, D02 Y754, Ireland	EU/1/04/295	6.12.2021.
6.12.2021.	RoActemra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/08/492	7.12.2021.
7.12.2021.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	7.12.2021.
8.12.2021.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	8.12.2021.
9.12.2021.	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbæk Strand, Danmark	EU/1/12/794	14.12.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
9.12.2021.	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	13.12.2021.
9.12.2021.	Amyvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/12/805	13.12.2021.
9.12.2021.	Apealea	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/18/1292	10.12.2021.
9.12.2021.	Chenodeoxycholic acid Leadiant	Leadiant GmbH Liebherrstr. 22, 80538 Munich, Deutschland	EU/1/16/1110	10.12.2021.
9.12.2021.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	10.12.2021.
9.12.2021.	Dengvaxia	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/18/1338	13.12.2021.
9.12.2021.	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	10.12.2021.
9.12.2021.	Esbriet	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/11/667	10.12.2021.
9.12.2021.	Exelon	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/066	10.12.2021.
9.12.2021.	Holoclar	Holostem Terapie Avanzate S.r.l. Via Glauco Gottardi 100, Modena, MO 41125, Italia	EU/1/14/987	13.12.2021.
9.12.2021.	JETREA	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/13/819	10.12.2021.
9.12.2021.	Leganto	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/11/695	10.12.2021.
9.12.2021.	Livogiva	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/20/1462	13.12.2021.
9.12.2021.	Ogluo	Tetris Pharma B.V Element Offices, Bargelaan 180-200, 2333 CW, Leiden, Nederland	EU/1/20/1523	13.12.2021.
9.12.2021.	Pioglitazone Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/722	10.12.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
9.12.2021.	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	14.12.2021.
9.12.2021.	Roteas	Berlin-Chemie AG Glienicker Weg 125, 12489 Berlin, Deutschland	EU/1/16/1152	15.12.2021.
9.12.2021.	Stalevo	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/03/260	10.12.2021.
9.12.2021.	Thalidomide BMS	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/08/443	10.12.2021.
9.12.2021.	Xospata	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/19/1399	10.12.2021.
9.12.2021.	ZALTRAP	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Pariz, France	EU/1/12/814	10.12.2021.
9.12.2021.	Zyprexa	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/96/022	13.12.2021.
9.12.2021.	Zyprexa Velotab	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/99/125	13.12.2021.
13.12.2021.	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbæk Strand, Danmark	EU/1/12/794	14.12.2021.
13.12.2021.	Conbriza	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/09/511	14.12.2021.
13.12.2021.	Giotrif	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/13/879	14.12.2021.
13.12.2021.	Invanz	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/02/216	14.12.2021.
13.12.2021.	Kanuma	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1033	14.12.2021.
13.12.2021.	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	14.12.2021.
13.12.2021.	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	14.12.2021.
13.12.2021.	Neulasta	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227	15.12.2021.
13.12.2021.	Neuraceq	Life Radiopharma Berlin GmbH Max-Planck-Straße 4, 12489 Berlin, Deutschland	EU/1/13/906	15.12.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
13.12.2021.	NULOJIX	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/694	14.12.2021.
13.12.2021.	Pramipexole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/728	16.12.2021.
13.12.2021.	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	17.12.2021.
13.12.2021.	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	15.12.2021.
13.12.2021.	Rebif	Merck Europe B.V. Gustav Mahlerplein 102, lto Toren, 1082 MA Amsterdam, Nederland	EU/1/98/063	17.12.2021.
13.12.2021.	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/09/599	15.12.2021.
13.12.2021.	Thalidomide BMS	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/08/443	14.12.2021.
13.12.2021.	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	15.12.2021.
16.12.2021.	Ceprotin	Baxter AG Industriestraße 67, 1221 Wien, Österreich	EU/1/01/190	17.12.2021.
16.12.2021.	Cinacalcet Accord-pharma	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1429	17.12.2021.
16.12.2021.	Clopidogrel Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	20.12.2021.
16.12.2021.	Clopidogrel Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/08/465	23.12.2021.
16.12.2021.	COVID-19 Vaccine Janssen	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1525	16.12.2021.
16.12.2021.	Dexdor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/718	19.12.2021.
16.12.2021.	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	17.12.2021.
16.12.2021.	Herzuma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/17/1257	20.12.2021.
16.12.2021.	Humira	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/03/256	17.12.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2021.	Jyseleca	Galapagos NV Generaal De Wittelaan L11 A3, 2800 Mechelen Antwerp, België	EU/1/20/1480	17.12.2021.
16.12.2021.	KANJINTI	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/18/1281	20.12.2021.
16.12.2021.	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	20.12.2021.
16.12.2021.	Revestive	Shire Pharmaceuticals Ireland Limited Blocks 2 & 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/12/787	23.12.2021.
16.12.2021.	Rinvoq	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	17.12.2021.
16.12.2021.	Sarclisa	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Pariz, France	EU/1/20/1435	17.12.2021.
16.12.2021.	Siklos	Addmedica 37 rue de Caumartin, 75009 Pariz, France	EU/1/07/397	17.12.2021.
16.12.2021.	Vemlidy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/16/1154	17.12.2021.
16.12.2021.	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	17.12.2021.
16.12.2021.	Zoely	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/11/690	21.12.2021.
16.12.2021.	Zoely	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/11/690	21.12.2021.
17.12.2021.	Kineret	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/02/203	17.12.2021.
20.12.2021.	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/15/1040	21.12.2021.
20.12.2021.	Nitisinone MDK	MendeliKABS Europe Limited Unit 3D, North Point House, North Point Business Park, New Mallow Road 9, Cork, T23 AT2P, Ireland	EU/1/17/1217	21.12.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
20.12.2021.	PANTOLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/519	21.12.2021.
20.12.2021.	Raloxifene Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/627	23.12.2021.
20.12.2021.	Selincro	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/12/815	21.12.2021.
20.12.2021.	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	20.12.2021.
20.12.2021.	Vorikonazol Hikma	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó n.º 8, 8 A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal	EU/1/15/1004	4.1.2022.

— **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
13.12.2021.	Leganto	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/11/695	4.1.2022.
20.12.2021.	PANTOLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/519	21.12.2021.
20.12.2021.	Rasilez HCT	Noden Pharma DAC D'Olier Chambers, 16 A D'Olier Street, Dublin 2, Ireland	EU/1/08/491	22.12.2021.
20.12.2021.	Ytracis	CIS bio international Boite Postale 32, 91192 Gif-sur-Yvette, France	EU/1/03/250	22.12.2021.

— **Izdavanje odobrenja za stavljanje u promet** (članak 38. 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
7.12.2021.	Imoxat	imidakloprid/ moksidektin	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/21/280	Otopina za nakapavanje	QP54AB52	9.12.2021.
7.12.2021.	Suiseng Diff/A	Inaktivirano cjepivo protiv Clostridioides difficile i Clostridium perfringens	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	Suspenzija za injekciju	QI09AB12	9.12.2021.
15.12.2021.	Zenalpha	medetomidin hidroklorid/vatinoksan hidroklorid	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/21/279	Otopina za injekciju	QN05CM99	16.12.2021.

— **Izmjena odobrenja za stavljanje u promet** (članak 38. 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
7.12.2021.	Circovac	CEVA-Phylaxia Co. Ltd Szállás u. 5, 1107 Budapest, Magyarország	EU/2/07/075	9.12.2021.
7.12.2021.	Stronghold Plus	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	13.12.2021.
13.12.2021.	Apoquel	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	15.12.2021.
15.12.2021.	Bravecto Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/18/224	16.12.2021.
15.12.2021.	Cardalis	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/12/142	16.12.2021.
15.12.2021.	Osurnia	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/14/170	16.12.2021.
15.12.2021.	Rabitec	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/219	16.12.2021.

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

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS