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 2022. do 28. veljače 2022.

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

(2022/C 144/01)

[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
14.2.2022.	Apexxnar	Cjepivo protiv pneumokoka, polisaharidno, konjugirano (20-valentno, adsorbirano)	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1612	Suspenzija za injekciju	J07AL02	15.2.2022.
14.2.2022.	Ngenla	Somatrogon	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1617	Otopina za injekciju	Pending	15.2.2022.
14.2.2022.	OKEDI	risperidon	Laboratorios Farmacéuticos Rovi, S.A. Julián Camarillo 35, 28037 Madrid, España	EU/1/21/1621	Prašak i otapalo za suspenziju za injekciju s produljenim oslobađanjem	N05AX08	15.2.2022.
14.2.2022.	Oxbryta	vokselotora	Global Blood Therapeutics Netherlands B.V. Strawinskylaan 3051, 1077 ZX Amsterdam, Noord-Holland, Nederland	EU/1/21/1622	Filmom obložena tableta	B06AX	15.2.2022.
14.2.2022.	Saphnelo	anifrolumab	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1623	Koncentrat za otopinu za infuziju	L04AA51	15.2.2022.
16.2.2022.	Kerendia	finerenon	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/21/1616	Filmom obložena tableta	C03DA05	17.2.2022.
16.2.2022.	Sapropterin Dipharma	sapropterin	Dipharma B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	EU/1/21/1620	Prašak za oralnu otopinu. Tableta za oralnu otopinu	A16AX07	17.2.2022.

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
16.2.2022.	Sitagliptin/Metformin hydrochloride Mylan	sitagliptin/metforminklorid	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1619	Filmom obložena tableta	A10BD07	21.2.2022.
16.2.2022.	Tepmetko	tepotinib	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/21/1596	Filmom obložena tableta	L01EX21	17.2.2022.
21.2.2022.	Ontilyv	opikapon	Bial – Portela & C[a], SA À Av. da Siderurgia Nacional, 4745-457 S. Mamede do Coronado, Portugal	EU/1/21/1578	Kapsula, tvrda	N04BX04	22.2.2022.

— **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
2.2.2022.	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	2.2.2022.
3.2.2022.	Clopidogrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	7.2.2022.
3.2.2022.	DaTSCAN	GE Healthcare B.V. De Rondom 8, 5612 AP, Eindhoven, Nederland	EU/1/00/135	9.2.2022.
3.2.2022.	Edarbi	Takeda Pharma A/S Delta Park 45, 2665 Vallensbæk Strand, Danmark	EU/1/11/734	8.2.2022.
3.2.2022.	Efavirenz/Emtricitabine/Tenofovir disoproxil Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1263	9.2.2022.
3.2.2022.	Nyxoid	Mundipharma Corporation (Ireland) Limited Millbank House, Arkle Road, Sandyford Industrial Estate, Dublin 18, Ireland	EU/1/17/1238	7.2.2022.
3.2.2022.	Pregabalin Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1021	8.2.2022.
3.2.2022.	Vivanza	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/249	7.2.2022.
3.2.2022.	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	4.2.2022.
3.2.2022.	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	4.2.2022.
4.2.2022.	Cialis	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/02/237	8.2.2022.
4.2.2022.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	4.2.2022.
4.2.2022.	Ebixa	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/02/219	8.2.2022.
4.2.2022.	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	7.2.2022.
4.2.2022.	Entacapone Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/665	8.2.2022.
4.2.2022.	HyQvia	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/13/840	7.2.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
4.2.2022.	Iressa	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/526	7.2.2022.
4.2.2022.	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/331	9.2.2022.
4.2.2022.	Noxafil	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/320	8.2.2022.
4.2.2022.	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	9.2.2022.
4.2.2022.	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	7.2.2022.
4.2.2022.	Roclanda	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/20/1502	10.2.2022.
4.2.2022.	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	8.2.2022.
4.2.2022.	Temozolomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/10/615	9.2.2022.
4.2.2022.	Vantobra	PARI Pharma GmbH Moosstraße 3, 82319 Starnberg, Deutschland	EU/1/18/1350	10.2.2022.
4.2.2022.	Yellox	BAUSCH + LOMB IRELAND LIMITED 3013 Lake Drive Citywest Business Campus Dublin 24, D24PPT3, Ireland	EU/1/11/692	14.2.2022.
4.2.2022.	Zoledronic acid Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/12/800	7.2.2022.
10.2.2022.	Ameluz	Biofrontera Bioscience GmbH Hemmelrather Weg 201, 51377 Leverkusen, Deutschland	EU/1/11/740	15.2.2022.
10.2.2022.	Axumin	Blue Earth Diagnostics Ireland Ltd 6th Floor, 2 Grand Canal Square, Dublin 2, Ireland	EU/1/17/1186	15.2.2022.
10.2.2022.	Cotellic	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/15/1048	14.2.2022.
10.2.2022.	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/18/1290	15.2.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.2.2022.	Wakix	Bioprojet Pharma 9 rue Rameau, 75002 Pariz, France	EU/1/15/1068	3.3.2022.
14.2.2022.	Cubicin	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/328	18.2.2022.
14.2.2022.	Incruse Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/922	4.3.2022.
14.2.2022.	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	15.2.2022.
14.2.2022.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	16.2.2022.
14.2.2022.	Waylivra	Akcea Therapeutics Ireland Limited Regus House, Harcourt Centre, Harcourt Road, Dublin 2, Ireland	EU/1/19/1360	21.2.2022.
14.2.2022.	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	17.2.2022.
16.2.2022.	AMGLIDIA	AMMTeK 55 rue de Turbigo, 75003 Pariz, France	EU/1/18/1279	16.2.2022.
16.2.2022.	Besponsa	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/17/1200	17.2.2022.
16.2.2022.	CellCept	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/96/005	17.2.2022.
16.2.2022.	Deltyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	17.2.2022.
16.2.2022.	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	17.2.2022.
16.2.2022.	ellaOne	Laboratoire HRA Pharma 200 avenue de Pariz, 92320 Chatillon, France	EU/1/09/522	23.2.2022.
16.2.2022.	Envarsus	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/935	21.2.2022.
16.2.2022.	Febuxostat Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	17.2.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.2.2022.	JEMPERLI	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	17.2.2022.
16.2.2022.	Laventair Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/899	4.3.2022.
16.2.2022.	Mayzent	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1414	17.2.2022.
16.2.2022.	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/09/523	17.2.2022.
16.2.2022.	Myclausen	Passauer Pharma GmbH Eiderstedter Weg 3, 14129 Berlin, Deutschland	EU/1/10/647	17.2.2022.
16.2.2022.	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	21.2.2022.
16.2.2022.	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	21.2.2022.
16.2.2022.	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	17.2.2022.
16.2.2022.	Temybric Ellipta	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/19/1378	4.3.2022.
16.2.2022.	Yuflyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/20/1513	2.3.2022.
16.2.2022.	Zykadia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/15/999	17.2.2022.
17.2.2022.	Advagraf	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/07/387	21.2.2022.
17.2.2022.	Avonex	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/97/033	23.2.2022.
17.2.2022.	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	18.2.2022.
17.2.2022.	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	21.2.2022.
17.2.2022.	Nexium Control	GlaxoSmithKline Dungarvan Limited Dungarvan, Co. Waterford, Ireland	EU/1/13/860	24.2.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
18.2.2022.	Tarceva	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/05/311	21.2.2022.
18.2.2022.	Zelboraf	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/12/751	21.2.2022.
21.2.2022.	Clopidogrel Taw Pharma	Taw Pharma (Ireland) Limited 104 Lower Baggot Street, Dublin 2, Ireland	EU/1/09/559	22.2.2022.
21.2.2022.	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	25.2.2022.
21.2.2022.	Ogivri	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1341	23.2.2022.
21.2.2022.	Refixia	Novo Nordisk A/S Novo Allé, 2880 Bagsværd, Danmark	EU/1/17/1193	24.2.2022.
21.2.2022.	Skilarence	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/17/1201	23.2.2022.
23.2.2022.	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	25.2.2022.
24.2.2022.	ADVATE	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/03/271	28.2.2022.
24.2.2022.	Bortezomib Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/16/1114	25.2.2022.
24.2.2022.	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	25.2.2022.
24.2.2022.	Irbesartan Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/576	28.2.2022.
24.2.2022.	JEVTANA	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Pariz, France	EU/1/11/676	28.2.2022.
24.2.2022.	Lakozamid UCB	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1383	25.2.2022.
24.2.2022.	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	25.2.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
24.2.2022.	Senshio	Shionogi B.V. Kingsfordweg 151, 1043 GR Amsterdam, Nederland	EU/1/14/978	25.2.2022.
28.2.2022.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	28.2.2022.
28.2.2022.	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	2.3.2022.
28.2.2022.	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	1.3.2022.
28.2.2022.	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	2.3.2022.
28.2.2022.	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	1.3.2022.

— **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
3.2.2022.	Vivanza	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/249	7.2.2022.

— **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
1.2.2022.	Bravecto	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/13/158	3.2.2022.
1.2.2022.	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	2.2.2022.
8.2.2022.	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	9.2.2022.
8.2.2022.	Zulvac 8 Ovis	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/09/104	9.2.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.2.2022.	Draxxin	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/03/041	16.2.2022.
10.2.2022.	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/98/006	14.2.2022.
10.2.2022.	Onsior	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/08/089	11.2.2022.
28.2.2022.	Innovax-ND-IBD	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/213	2.3.2022.
28.2.2022.	Innovax-ND-ILT	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/20/256	2.3.2022.

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