IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2021. gada 1. decembra līdz 2021. gada 31. decembrim

(Publicēts saskaņā ar Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 ([1]) 13. vai 38. pantu)

(2022/C 50/01)

([1]) OV L 136, 30.4.2004., 1. lpp.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	*INN* (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
9.12.2021.	Cibinqo	abrocitinibs	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	Apvalkotās tabletes	D11AH	10.12.2021.
9.12.2021.	Rybrevant	amivantamabs	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	Koncentrāts infūziju šķīduma pagatavošanai	L01FX18	10.12.2021.
9.12.2021.	Sitagliptin SUN	sitagliptīna fumarāts	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/21/1598	Apvalkotās tabletes	A10BH01	15.12.2021.
13.12.2021.	ASPAVELI	pegcetacoplan	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	Šķīdums infūzijām	L04AA54	14.12.2021.
13.12.2021.	Vaxneuvance	Pneimokoku polisaharīdu konjugēta vakcīna (15-valenta, adsorbēta)	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1591	Suspensija injekcijai	J07AL	14.12.2021.
17.12.2021.	Xevudy	sotrovimabs	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	Koncentrāts infūziju šķīduma pagatavošanai	Pending	17.12.2021.
20.12.2021.	Nuvaxovid	COVID-19 vakcīna (rekombinanta, ar adjuvantu)	Novavax CZ, a.s. Bohumil 138, 281 63 Jevany, Česká republika	EU/1/21/1618	Dispersija injekcijām	J07BX03	20.12.2021.

— **Tirdzniecības atļaujas grozīšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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 Paris, 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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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 Paris, 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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, Ito 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 Accordpharma	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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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 Paris, France	EU/1/20/1435	17.12.2021.
16.12.2021.	Siklos	Addmedica 37 rue de Caumartin, 75009 Paris, 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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.	Voriconazole Hikma	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó n.º 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal	EU/1/15/1004	4.1.2022.

— **Tirdzniecības atļaujas izņemšana no aprites** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants)

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, 16A 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.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 38. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	*INN* (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
7.12.2021.	Imoxat	imidakloprīds/moksidektīns	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/21/280	Spot-on šķīdums	QP54AB52	9.12.2021.
7.12.2021.	Suiseng Diff/A	*Clostridioides difficile* un *Clostridium perfringens* vakcīna, inaktivēta	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	Suspensija injekcijai	QI09AB12	9.12.2021.
15.12.2021.	Zenalpha	medetomidīna hidrohlorīds/vatinoksāna hidrohlorīds	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/21/279	Šķīdums injekcijai	QN05CM99	16.12.2021.

— **Tirdzniecības atļaujas grozīšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 38. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Ikvienam, kurš vēlas apskatīt publisko novērtējuma ziņojumu par attiecīgajām zālēm un ar tām saistītos lēmumus, jāsazinās ar:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS