ELI: http://data.europa.eu/eli/C/2024/3355/oj

Povzetek sklepov Evropske unije o dovoljenjih za promet z zdravili od 1. april 2024 do 30. april 2024

(Objavljeno v skladu s členom 13 ali členom 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta ([1]) ali Člen 5 Uredbe (EU) 2019/6 Evropskega parlamenta in Sveta ([2]))

(C/2024/3355)

— **Izdaja dovoljenja za promet** (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
19.4.2024	Apremilast Accord	apremilast	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1796	Filmsko obložene tablete	L04AA32	23.4.2024
19.4.2024	CARVYKTI	ciltakabtagen avtolevcel	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	Disperzija za infundiranje	L01XL05	22.4.2024
19.4.2024	Celldemic	Cepivo proti zoonotični gripi (H5N1) (površinski antigen, inaktiviran, z adjuvansom, pripravljen v celičnih kulturah)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1806	suspenzija za injiciranje v napolnjeni injekcijski brizgi (injekcija)	J07BB02	22.4.2024
19.4.2024	Filspari	sparsentan	Vifor France S.A. Tour Franklin La Defense 8, 100-101 Terrasse Boieldieu, 92042 Paris La Defense Cedex, France	EU/1/23/1788	Filmsko obložene tablete	C09XX01	23.4.2024

([1]) UL L 136, 30.4.2004, str. 1.
([2]) UL L 4, 7.1.2019, str. 43.

19.4.2024	Incellipan	Pandemično cepivo proti gripi (H5N1) (površinski antigen, inaktiviran, z adjuvansom, pripravljen v celičnih kulturah)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1807	Suspenzija za injiciranje	J07BB02	23.4.2024
19.4.2024	Nintedanib Accord	nintedanib	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1803	Kapsula, mehka	L01EX09	24.4.2024
19.4.2024	Pyzchiva	ustekinumab	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1801	koncentrat za raztopino za injiciranje Rztopina za injiciranje	L04AC05	24.4.2024
19.4.2024	Tizveni	tislelizumab	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/24/1797	Koncentrat za raztopino za infundiranje		22.4.2024
19.4.2024	Voydeya	danikopan	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/24/1792	Filmsko obložene tablete	L04AJ09	25.4.2024
19.4.2024	ZYNYZ	retifanlimab	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/24/1800	Koncentrat za raztopino za infundiranje	L01FF10	24.4.2024
22.4.2024	Dimethyl fumarate Mylan		Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/24/1814	Gastrorezistentna kapsula, trda	L04AX07	24.4.2024

22.4.2024	Dimethyl fumarate Neuraxpharm	dimetilfumarat	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1810	Gastrorezistentna kapsula, trda	L04AX07	22.4.2024
22.4.2024	Dimetilfumarat Accord	dimetilfumarat	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1811	Gastrorezistentna kapsula, trda	L04AX07	22.4.2024
22.4.2024	Emblaveo	aztreonam / avibaktam	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1808	Prašek za koncentrat za raztopino za infundiranje	J01DF51	22.4.2024

— **Sprememba dovoljenja za promet** (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
5.4.2024	Alofisel	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/17/1261	8.4.2024
5.4.2024	Clopidogrel/Acetylsalicylic acid Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	8.4.2024
5.4.2024	Entecavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1227	8.4.2024
5.4.2024	Epidyolex	Jazz Pharmaceuticals Ireland Ltd 5th Floor, Waterloo Exchange, Waterloo Road, Dublin D04 E5W7, Ireland	EU/1/19/1389	8.4.2024
5.4.2024	Febuxostat Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	8.4.2024
5.4.2024	Lakozamid UCB	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1383	8.4.2024
5.4.2024	Lokelma	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1173	8.4.2024
5.4.2024	Lorviqua	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	8.4.2024
5.4.2024	Orkambi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/15/1059	8.4.2024
5.4.2024	Perjeta	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/813	8.4.2024
9.4.2024	Anagrelide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/17/1256	10.4.2024

9.4.2024	Clopidogrel/Acetylsalicylic acid Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	10.4.2024
9.4.2024	Drovelis	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/21/1547	11.4.2024
9.4.2024	Entecavir Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1227	10.4.2024
9.4.2024	Febuxostat Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1194	10.4.2024
9.4.2024	Inhixa	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077 XX Amsterdam, Nederland	EU/1/16/1132	15.4.2024
9.4.2024	Orfadin	Swedish Orphan Biovitrum International AB 112 76 Stockholm, Sverige	EU/1/04/303	11.4.2024
9.4.2024	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	10.4.2024
9.4.2024	Posaconazole AHCL	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1380	10.4.2024
9.4.2024	Prasugrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1273	10.4.2024
9.4.2024	Zalasta	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/07/415	15.4.2024
9.4.2024	Zeposia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1442	10.4.2024
9.4.2024	Zoonotic Influenza Vaccine Seqirus	Seqirus S.r.l. Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italia	EU/1/23/1761	10.4.2024
11.4.2024	Fingolimod Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1573	15.4.2024

15.4.2024	Moventig	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/14/962	17.4.2024
15.4.2024	Talzenna	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1377	16.4.2024
19.4.2024	Atazanavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1091	22.4.2024
19.4.2024	Biktarvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/18/1289	22.4.2024
19.4.2024	Bimzelx	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/21/1575	23.4.2024
19.4.2024	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	23.4.2024
19.4.2024	Emtricitabin/dizoproksiltenofovirat Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1148	22.4.2024
19.4.2024	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	23.4.2024
19.4.2024	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	22.4.2024
19.4.2024	Koselugo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1552	22.4.2024
19.4.2024	Lamivudine Teva Pharma B.V.	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/596	22.4.2024
19.4.2024	Leqvio	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1494	23.4.2024

19.4.2024	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	22.4.2024
19.4.2024	Lyxumia	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/12/811	22.4.2024
19.4.2024	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	22.4.2024
19.4.2024	Onglyza	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/545	22.4.2024
19.4.2024	Palynziq	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/19/1362	22.4.2024
19.4.2024	Pandemic influenza vaccine H5N1 AstraZeneca	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1089	22.4.2024
19.4.2024	Pluvicto	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1703	26.4.2024
19.4.2024	Potactasol	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/10/660	23.4.2024
19.4.2024	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	22.4.2024
19.4.2024	Qtern	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1108	22.4.2024
19.4.2024	Rivastigmine Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/693	25.4.2024
19.4.2024	Sivextro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/991	22.4.2024
19.4.2024	Spedra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/13/841	23.4.2024
19.4.2024	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	22.4.2024

19.4.2024	Teriflunomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1693	24.4.2024
19.4.2024	Twinrix za odrasle	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/96/020	24.4.2024
19.4.2024	Twinrix za otroke	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/97/029	24.4.2024
19.4.2024	Ultomiris	Alexion Europe SAS 103-105 Rue Anatole France, 92300 Levallois-Perret, France	EU/1/19/1371	29.4.2024
19.4.2024	Xeplion	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/11/672	22.4.2024
19.4.2024	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/13/846	25.4.2024
25.4.2024	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/02/224	26.4.2024
25.4.2024	BYANNLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1453	26.4.2024
25.4.2024	Colobreathe	Essential Pharma Limited Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara CBD 1070, Malta	EU/1/11/747	30.4.2024
25.4.2024	Granpidam	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/16/1137	26.4.2024
25.4.2024	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/12/782	26.4.2024

25.4.2024	Krazati	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1744	6.5.2024
25.4.2024	Levetiracetam Actavis Group	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/738	26.4.2024
25.4.2024	Lydisilka	Estetra SRL Rue Saint Georges 5-7, 4000 Liège, Belgique	EU/1/21/1548	26.4.2024
25.4.2024	LysaKare	Advanced Accelerator Applications 8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France	EU/1/19/1381	26.4.2024
25.4.2024	Onivyde pegylated liposomal	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes Cedex, France	EU/1/16/1130	30.4.2024
25.4.2024	Yselty	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/21/1606	29.4.2024
29.4.2024	Luxturna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1331	1.5.2024
29.4.2024	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	6.5.2024
29.4.2024	Xerava	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/18/1312	6.5.2024

— **Ukinitev dovoljenja za promet** (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta)

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
19.4.2024	Telmisartan Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/719	22.4.2024

— **Izdaja dovoljenja za promet** (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta; Člen 5 Uredbe (EU) 2019/6 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
8.4.2024	Alcort	osateronijevega acetata	NEXTMUNE ITALY S.R.L. Via G.B. Benzoni 50, 26020 Palazzo Pignano (CR), Italia	EU/2/24/306	Razpršilo za kožo, raztopina	QD07AC16	9.4.2024
8.4.2024	Lexylan	cefaleksin	Emdoka John Lijsenstraat 16, 2321 Hoogstraten, België	EU/2/24/308	Suspenzija za injiciranje	QJ01DB01	10.4.2024
9.4.2024	DIVENCE PENTA	(Živo) cepivo za govejo virusno diarejo (podenota), virus goveje parainfluence 3 (inaktiviran), goveji respiratorni sincicijski virus in goveji herpesvirus tipa 1	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/307	Liofilizat in vehikel za raztopino za injiciranje	QI02AH	10.4.2024
25.4.2024	Lotimax	lotilaner	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/24/311	Žvečljive tablete	QP53BE04	29.4.2024

ELI: http://data.europa.eu/eli/C/2024/3355/oj

— **Sprememba dovoljenja za promet** (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta; Člen 5 Uredbe (EU) 2019/6 Evropskega parlamenta in Sveta): **Odobrena**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
8.4.2024	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	12.4.2024
8.4.2024	Chanhold	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/19/236	15.4.2024
8.4.2024	Daxocox	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/21/270	9.4.2024
8.4.2024	Draxxin	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/03/041	10.4.2024
8.4.2024	Incurin	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/018	11.4.2024
9.4.2024	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	12.4.2024
9.4.2024	Lydaxx	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/253	10.4.2024
9.4.2024	OvuGel	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/260	10.4.2024
9.4.2024	Strangvac	Intervacc AB Vastertorpsvagen 135, 129 44 Hagersten, Sverige	EU/2/21/274	10.4.2024
11.4.2024	Tulissin	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/20/252	12.4.2024
25.4.2024	Halocur	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/99/013	26.4.2024
25.4.2024	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/14/174	29.4.2024

25.4.2024	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	30.4.2024
25.4.2024	Purevax RCP	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/052	29.4.2024
25.4.2024	Senvelgo	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/23/305	29.4.2024
25.4.2024	Tulaven	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/251	26.4.2024
29.4.2024	Coliprotec F4/F18	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/16/202	30.4.2024

Kdor želi dobiti vpogled v javno poročilo o oceni zadevnih zdravil ter o zadevnih sklepih o zdravilih, se lahko obrne na naslov:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS