ELI: http://data.europa.eu/eli/C/2024/2791/oj

Službeni list Europske unije

C/2024/2791

30.4.2024.

HR
Serija C

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. ožujka 2024. do 31. ožujka 2024.

(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ([1]) *ili člankom 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća* ([2]))

(C/2024/2791)

- **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
19.03.2024	Abecma	idecabtagene vicleucel	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	Disperzija za infuziju	L01	22.03.2024
21.03.2024	EXBLIFEP	cefepime/ enmetazobaktam	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Co. Dublin, Ireland	EU/1/24/1794	Prašak za koncentrat za otopinu za infuziju	J01DE51	23.03.2024
21.03.2024	Niapelf	Paliperidon	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1795	Suspenzija s produljenim oslobađanjem za injekciju	N05AX13	02.04.2024
21.03.2024	Ryzneuta	efbemalenograstim alfa	Evive Biotechnology Ireland LTD Second Floor, Joshua Dawson House, Dawson Street, Dublin, D02 RY95, Ireland	EU/1/24/1793	Otopina za injekciju	L03AA18	22.03.2024

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

- **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
01.03.2024	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, 1831 Diegem, België	EU/1/08/473	06.03.2024
01.03.2024	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, D02 R296, Ireland	EU/1/18/1290	04.03.2024
01.03.2024	Pepaxti	Oncopeptides AB (publ) Luntmakargatan 46, 111 37 Stockholm, Sverige	EU/1/22/1669	04.03.2024
01.03.2024	Zercepac	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1456	04.03.2024
01.03.2024	Zoledronic acid Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/759	04.03.2024
11.03.2024	CARVYKTI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	13.03.2024
11.03.2024	Ecansya	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	12.03.2024
11.03.2024	Ondexxya	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1345	12.03.2024
11.03.2024	Prevenar 20	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1612	12.03.2024
11.03.2024	Striascan	CIS bio international RN 306 – Saclay, B.P. 32, F-91192 Gif-sur-Yvette Cedex, France	EU/1/19/1372	12.03.2024
11.03.2024	Upstaza	PTC Therapeutics International Limited 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/22/1653	12.03.2024
11.03.2024	Waylivra	Akcea Therapeutics Ireland Ltd St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland	EU/1/19/1360	12.03.2024

14.03.2024	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419	15.03.2024
14.03.2024	Epysqli	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/23/1735	19.03.2024
14.03.2024	Firazyr	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/08/461	15.03.2024
14.03.2024	Inbrija	Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/19/1390	21.03.2024
14.03.2024	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	04.04.2024
14.03.2024	JEVTANA	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/11/676	15.03.2024
14.03.2024	Mozobil	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/09/537	15.03.2024
14.03.2024	Tarceva	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/05/311	15.03.2024
14.03.2024	Yargesa	Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland	EU/1/17/1176	19.03.2024
14.03.2024	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	15.03.2024
18.03.2024	Mekinist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/931	20.03.2024
19.03.2024	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	21.03.2024

19.03.2024	Fintepla	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/20/1491	21.03.2024
19.03.2024	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	20.03.2024
19.03.2024	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	20.03.2024
19.03.2024	Qarziba	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1191	22.03.2024
19.03.2024	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	20.03.2024
21.03.2024	Aldurazyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/03/253	22.03.2024
21.03.2024	Ambrisentan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1368	25.03.2024
21.03.2024	BIMERVAX	Hipra Human Health, S.L.U. Avda. la Selva, 135, 17170 Amer (Girona), España	EU/1/22/1709	22.03.2024
21.03.2024	Celdoxome pegylated liposomal	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/22/1666	02.04.2024
21.03.2024	Cibinqo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	22.03.2024
21.03.2024	Clopidogrel ratiopharm	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/14/975	26.03.2024
21.03.2024	Dovato	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/19/1370	22.03.2024
21.03.2024	Enjaymo	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/22/1687	27.03.2024

21.03.2024	Giapreza	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/19/1384	22.03.2024
21.03.2024	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	22.03.2024
21.03.2024	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	22.03.2024
21.03.2024	Nemdatine	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/13/824	22.03.2024
21.03.2024	Nexviadyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1579	27.03.2024
21.03.2024	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	22.03.2024
21.03.2024	Spikevax	MODERNA BIOTECH SPAIN, S.L.	EU/1/20/1507	25.03.2024
21.03.2024	Tepadina	ADIENNE S.r.l.S.U. Via Galileo Galilei 19, 20867 Caponago (MB), Italia	EU/1/10/622	25.03.2024
21.03.2024	Uplizna	Horizon Therapeutics Ireland DAC 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland	EU/1/21/1602	22.03.2024
21.03.2024	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	22.03.2024
25.03.2024	ABILIFY MAINTENA	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/13/882	05.04.2024
25.03.2024	Aerinaze	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/07/399	26.03.2024
25.03.2024	CellCept	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/96/005	26.03.2024

25.03.2024	GAVRETO	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	26.03.2024
25.03.2024	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	02.04.2024
25.03.2024	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	26.03.2024
25.03.2024	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	26.03.2024
25.03.2024	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	26.03.2024
25.03.2024	PecFent	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/10/644	27.03.2024
25.03.2024	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	26.03.2024
25.03.2024	Sutent	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/347	26.03.2024
25.03.2024	Zolgensma	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1443	27.03.2024
26.03.2024	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	02.04.2024
27.03.2024	Anagrelide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/17/1256	02.04.2024
27.03.2024	Brilique	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/655	02.04.2024
27.03.2024	Cetrotide	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/99/100	03.04.2024

27.03.2024	Effentora	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/441	03.04.2024
27.03.2024	Febuxostat Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1347	04.04.2024
27.03.2024	Instanyl	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/09/531	03.04.2024
27.03.2024	Myclausen	Passauer Pharma GmbH Eiderstedter Weg 3, 14129 Berlin, Deutschland	EU/1/10/647	04.04.2024
27.03.2024	Nexium Control	GlaxoSmithKline Dungarvan Limited Dungarvan, Co. Waterford, Ireland	EU/1/13/860	02.04.2024
27.03.2024	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	02.04.2024
27.03.2024	Prasugrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1273	02.04.2024
27.03.2024	Puregon	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/96/008	02.04.2024
27.03.2024	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	02.04.2024
27.03.2024	Repatha	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1016	02.04.2024
27.03.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	03.04.2024
27.03.2024	Segluromet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1265	02.04.2024
27.03.2024	Sixmo	L. Molteni & C. dei F.lli Alitti Società di .Esercizio .S.p.A Strada Statale 67, Loc. Granatieri, 50018 Scandicci (Firenze), Italia	EU/1/19/1369	02.04.2024

27.03.2024	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	02.04.2024
27.03.2024	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	02.04.2024

- **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
01.03.2024	Zoledronic acid Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/759	04.03.2024
11.03.2024	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	12.03.2024
27.03.2024	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	02.04.2024

- **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
11.03.2024	Profender	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/05/054	12.03.2024
21.03.2024	Baycox Iron	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/239	22.03.2024
21.03.2024	ReproCyc ParvoFLEX	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/19/237	25.03.2024
27.03.2024	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	02.04.2024

27.03.2024	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	02.04.2024
27.03.2024	Suprelorin	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/07/072	02.04.2024

- **Povlačenje 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)

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
27.03.2024	Bovilis Blue-8	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/218	02.04.2024
27.03.2024	Enteroporc Coli	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/268	02.04.2024

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
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