Europos Sąjungos oficialusis leidinys
C/2024/2791
2024 4 30
LT
C serija

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2024 m. kovo 1 d. iki 2024 m. kovo 31 d.

(Paskelbta pagal Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 ([1]) 13 straipsnį arba 38 straipsnį arba Europos Parlamento ir Tarybos reglamento (ES) 2019/6 ([2]) 5 straipsnį)

(C/2024/2791)

— **Rinkodaros leidimo suteikimas** (Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 13 straipsnis): **Priimta**

Sprendimo data	Vaisto pavadinimas	INN (Tarptautinis nepatentuotas pavadinimas)	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Farmacinė forma	ATC kodas (Anatominis terapinis cheminis kodas)	Pranešimo data
2024 3 19	Abecma	idekabtagenas vikleucelas	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	Infuzinė dispersija	L01	2024 3 22
2024 3 21	EXBLIFEP	cefepimas / enmetazobaktamas	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Co. Dublin, Ireland	EU/1/24/1794	Milteliai koncentratui infuziniam tirpalui	J01DE51	2024 3 23
2024 3 21	Niapelf	Paliperidonas	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1795	Pailginto atpalaidavimo injekcinė suspensija	N05AX13	2024 4 2
2024 3 21	Ryzneuta	efbemalenograstimas alfa	Evive Biotechnology Ireland LTD Second Floor, Joshua Dawson House, Dawson Street, Dublin, D02 RY95, Ireland	EU/1/24/1793	Injekcinis tirpalas	L03AA18	2024 3 22

([1]) OL L 136, 2004 4 30, p. 1.
([2]) OL L 4, 2019 1 7, p. 43.

— **Rinkodaros leidimo pakeitimas** (Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 13 straipsnis): **Priimta**

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2024 3 1	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, 1831 Diegem, België	EU/1/08/473	2024 3 6
2024 3 1	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, D02 R296, Ireland	EU/1/18/1290	2024 3 4
2024 3 1	Pepaxti	Oncopeptides AB (publ) Luntmakargatan 46, 111 37 Stockholm, Sverige	EU/1/22/1669	2024 3 4
2024 3 1	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	2024 3 4
2024 3 1	Zoledronic acid Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/759	2024 3 4
2024 3 11	CARVYKTI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	2024 3 13
2024 3 11	Ecansya	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	2024 3 12
2024 3 11	Ondexxya	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1345	2024 3 12
2024 3 11	Prevenar 20	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1612	2024 3 12
2024 3 11	Striascan	CIS bio international RN 306 – Saclay, B.P. 32, F-91192 Gif-sur-Yvette Cedex, France	EU/1/19/1372	2024 3 12
2024 3 11	Upstaza	PTC Therapeutics International Limited 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/22/1653	2024 3 12
2024 3 11	Waylivra	Akcea Therapeutics Ireland Ltd St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland	EU/1/19/1360	2024 3 12

2024 3 14	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419	2024 3 15
2024 3 14	Epysqli	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/23/1735	2024 3 19
2024 3 14	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	2024 3 15
2024 3 14	Inbrija	Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/19/1390	2024 3 21
2024 3 14	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	2024 4 4
2024 3 14	JEVTANA	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/11/676	2024 3 15
2024 3 14	Mozobil	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/09/537	2024 3 15
2024 3 14	Tarceva	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/05/311	2024 3 15
2024 3 14	Yargesa	Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland	EU/1/17/1176	2024 3 19
2024 3 14	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	2024 3 15
2024 3 18	Mekinist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/931	2024 3 20
2024 3 19	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	2024 3 21

2024 3 19	Fintepla	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/20/1491	2024 3 21
2024 3 19	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	2024 3 20
2024 3 19	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	2024 3 20
2024 3 19	Qarziba	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1191	2024 3 22
2024 3 19	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	2024 3 20
2024 3 21	Aldurazyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/03/253	2024 3 22
2024 3 21	Ambrisentan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1368	2024 3 25
2024 3 21	BIMERVAX	Hipra Human Health, S.L.U. Avda. la Selva, 135, 17170 Amer (Girona), España	EU/1/22/1709	2024 3 22
2024 3 21	Celdoxome pegylated liposomal	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/22/1666	2024 4 2
2024 3 21	Cibinqo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	2024 3 22
2024 3 21	Clopidogrel ratiopharm	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/14/975	2024 3 26
2024 3 21	Dovato	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/19/1370	2024 3 22
2024 3 21	Enjaymo	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/22/1687	2024 3 27

2024 3 21	Giapreza	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/19/1384	2024 3 22
2024 3 21	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	2024 3 22
2024 3 21	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	2024 3 22
2024 3 21	Nemdatine	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/13/824	2024 3 22
2024 3 21	Nexviadyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1579	2024 3 27
2024 3 21	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	2024 3 22
2024 3 21	Spikevax	MODERNA BIOTECH SPAIN, S.L.	EU/1/20/1507	2024 3 25
2024 3 21	Tepadina	ADIENNE S.r.l.S.U. Via Galileo Galilei 19, 20867 Caponago (MB), Italia	EU/1/10/622	2024 3 25
2024 3 21	Uplizna	Horizon Therapeutics Ireland DAC 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland	EU/1/21/1602	2024 3 22
2024 3 21	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	2024 3 22
2024 3 25	ABILIFY MAINTENA	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/13/882	2024 4 5
2024 3 25	Aerinaze	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/07/399	2024 3 26
2024 3 25	CellCept	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/96/005	2024 3 26

2024 3 25	GAVRETO	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	2024 3 26
2024 3 25	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	2024 4 2
2024 3 25	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	2024 3 26
2024 3 25	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	2024 3 26
2024 3 25	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	2024 3 26
2024 3 25	PecFent	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/10/644	2024 3 27
2024 3 25	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	2024 3 26
2024 3 25	Sutent	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/347	2024 3 26
2024 3 25	Zolgensma	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1443	2024 3 27
2024 3 26	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	2024 4 2
2024 3 27	Anagrelide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/17/1256	2024 4 2
2024 3 27	Brilique	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/655	2024 4 2
2024 3 27	Cetrotide	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/99/100	2024 4 3

2024 3 27	Effentora	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/441	2024 4 3
2024 3 27	Febuxostat Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1347	2024 4 4
2024 3 27	Instanyl	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/09/531	2024 4 3
2024 3 27	Myclausen	Passauer Pharma GmbH Eiderstedter Weg 3, 14129 Berlin, Deutschland	EU/1/10/647	2024 4 4
2024 3 27	Nexium Control	GlaxoSmithKline Dungarvan Limited Dungarvan, Co. Waterford, Ireland	EU/1/13/860	2024 4 2
2024 3 27	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	2024 4 2
2024 3 27	Prasugrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1273	2024 4 2
2024 3 27	Puregon	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/96/008	2024 4 2
2024 3 27	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	2024 4 2
2024 3 27	Repatha	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1016	2024 4 2
2024 3 27	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	2024 4 3
2024 3 27	Segluromet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1265	2024 4 2
2024 3 27	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	2024 4 2

2024 3 27	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	2024 4 2
2024 3 27	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	2024 4 2

— **Rinkodaros leidimo atšaukimas** (Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 13 straipsnis)

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2024 3 1	Zoledronic acid Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/759	2024 3 4
2024 3 11	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	2024 3 12
2024 3 27	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	2024 4 2

— **Rinkodaros leidimo pakeitimas** (Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 38 straipsnis; Europos Parlamento ir Tarybos reglamento (ES) 2019/6 5 straipsnis): **Priimta**

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2024 3 11	Profender	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/05/054	2024 3 12
2024 3 21	Baycox Iron	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/239	2024 3 22
2024 3 21	ReproCyc Parvo-FLEX	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/19/237	2024 3 25
2024 3 27	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	2024 4 2

2024 3 27	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	2024 4 2
2024 3 27	Suprelorin	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/07/072	2024 4 2

— **Rinkodaros leidimo atšaukimas** (Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 38 straipsnis; Europos Parlamento ir Tarybos reglamento (ES) 2019/6 5 straipsnis)

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2024 3 27	Bovilis Blue-8	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/218	2024 4 2
2024 3 27	Enteroporc Coli	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/268	2024 4 2

Norintieji susipažinti su nagrinėjamųjų vaistų vieša vertinimo ataskaita ir su ja susijusiais sprendimais, gali kreiptis į:

European Medicines Agency
Domenico Scarlattilaan 6
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