IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2014 m. gruodžio 1 d. iki 2014 m. gruodžio 31 d.

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

(2015/C 032/01)

([1]) OL L 136, 2004 4 30, p. 1.

— **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
2014 12 5	Paliperidone Janssen	Paliperidons	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/971	Pailginto atpalaidavimo injekcinė suspensija	N05AX13	2014 12 9
2014 12 8	Duloxetine Lilly	duloksetinas	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/972	Skrandyje neirios kapsulės, kietos	N06AX21	2014 12 10
2014 12 8	Moventig	naloksegolas	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/962	Plėvele dengta tabletė	A06AH03	2014 12 10
2014 12 16	DUAVIVE	konjuguoti estrogenai/bazedoksifenas	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/14/960	Modifikuoto atpalaidavimo tabletė	G03CX	2014 12 18
2014 12 16	Lynparza	Olaparibas	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/959	Kieta kapsulė	L01	2014 12 18
2014 12 19	Cyramza	ramucirumabas	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/957	Koncentratas infuziniam tirpalui	L01XC	2014 12 23
2014 12 19	Rixubis	nonakogas gama	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/14/970	Milteliai ir tirpiklis injekciniam tirpalui	B02BD04	2014 12 23
2014 12 22	Scenesse	afamelanotidas	Clinuvel UK Limited c/o – Reed Smith, Broadgate Tower, Third Floor, 20 Primrose Street, London, EC2A 2RS, United Kingdom	EU/1/14/969	Implantas	D02BB02	2014 12 29

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Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2014 12 1	Desloratadine Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/11/732	2014 12 3
2014 12 1	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/10/642	2014 12 3
2014 12 1	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/576	2014 12 3
2014 12 1	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	EU/1/07/398	2014 12 3
2014 12 4	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614	2014 12 9
2014 12 4	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444	2014 12 8
2014 12 4	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/445	2014 12 8
2014 12 5	Cystagon	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/97/039	2014 12 9
2014 12 5	Erbitux	Merck KGaA 64271 Darmstadt, Deutschland	EU/1/04/281	2014 12 9
2014 12 5	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	2014 12 9
2014 12 11	Bronchitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire SL1 7LW, United Kingdom	EU/1/12/760	2014 12 15
2014 12 11	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	2014 12 15

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2014 12 11	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	2014 12 15
2014 12 11	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/11/702	2014 12 15
2014 12 11	Removab	Neovii Biotech GmbH Am Haag 6-7, 82166 Graefelfing, Deutschland	EU/1/09/512	2014 12 15
2014 12 15	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134	2014 12 18
2014 12 15	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	2014 12 17
2014 12 15	Levetiracetam Actavis Group	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/738	2014 12 18
2014 12 15	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400	2014 12 18
2014 12 15	Naglazyme	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/05/324	2014 12 17
2014 12 15	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	2014 12 18
2014 12 15	Revestive	NPS Pharma Holdings Limited Grand Canal House, 1 Grand Canal Street Upper, Dublin 4, Ireland	EU/1/12/787	2014 12 17
2014 12 15	Somatropin Biopartners	BioPartners GmbH Kaiserpassage 11, D-72764 Reutlingen, Deutschland	EU/1/13/849	2014 12 17
2014 12 15	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/422	2014 12 18
2014 12 15	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	2014 12 18
2014 12 16	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538	2014 12 18

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2014 12 16	Brintellix	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/13/891	2014 12 18
2014 12 16	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	2014 12 17
2014 12 16	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/00/170	2014 12 18
2014 12 16	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/11/687	2014 12 18
2014 12 16	HyQvia	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/13/840	2014 12 18
2014 12 16	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720	2014 12 18
2014 12 16	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	2014 12 18
2014 12 16	Levetiracetam Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/713	2014 12 18
2014 12 16	Metiltioninio chloridas Proveblue	Provepharm S.A.S. 22 Rue Marc Donadille, 13013 Marseille, France	EU/1/11/682	2014 12 18
2014 12 16	NULOJIX	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/694	2014 12 18
2014 12 16	Orphacol	Laboratoires CTRS 63 rue de l'Est, F-92100 Boulogne-Billancourt, France	EU/1/13/870	2014 12 18
2014 12 16	Paglitaz	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/721	2014 12 18
2014 12 16	Pioglitazone Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/757	2014 12 18
2014 12 16	Pioglitazone Teva Pharma	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/758	2014 12 18
2014 12 16	Remsima	Celltrion Healthcare Hungary Kft. Árpád Fejedelem útja 26-28, H-1023 Budapest, Magyarország	EU/1/13/853	2014 12 18

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2014 12 16	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	2014 12 19
2014 12 16	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	2014 12 17
2014 12 16	Stivarga	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/13/858	2014 12 18
2014 12 16	Ultibro Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/862	2014 12 18
2014 12 16	Ulunar Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/14/917	2014 12 19
2014 12 16	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	2014 12 18
2014 12 16	Xoterna Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/863	2014 12 18
2014 12 16	Zelboraf	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/12/751	2014 12 19
2014 12 19	CellCept	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/005	2014 12 23
2014 12 19	InductOs	Medtronic BioPharma B.V. Earl Bakkenstraat 10, NL-6422 PJ Heerlen, Nederland	EU/1/02/226	2014 12 23
2014 12 19	Puregon	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/008	2014 12 23
2014 12 19	Rilutek	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony CEDEX, France	EU/1/96/010	2014 12 23
2014 12 19	Stayveer	Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland	EU/1/13/832	2015 1 5
2014 12 19	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/610	2014 12 24
2014 12 19	Travatan	Alcon Laboratories (UK) Ltd Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom	EU/1/01/199	2014 12 23
2014 12 19	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	2014 12 23
2014 12 19	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	2014 12 24
2014 12 19	Zoledronic acid Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/772	2014 12 24

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2014 12 22	Bovela	modifikuoto gyvo necitopatinės tėvinės KE-9 padermės GVDV-1, modifikuoto gyvo necitopatinės tėvinės NY-93padermės GVDV-2	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/176	Liofilizatas ir tirpiklis injekcinei suspensijai ruošti	QI02AD02	2014 12 29

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Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2014 12 4	Gripovac 3	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/09/102	2014 12 8
2014 12 4	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/00/026	2014 12 8
2014 12 4	Respiporc Flu3	IDT Biologika GmbH Am Pharmapark, D-06861 Dessau-Rosslau, Deutschland	EU/2/09/103	2014 12 8
2014 12 11	Comfortis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/10/115	2014 12 15
2014 12 11	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/13/155	2014 12 15
2014 12 16	Pexion	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/12/147	2014 12 18

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

The European Medicines Agency
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