IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2017 m. vasario 1 d. iki 2017 m. vasario 28 d.

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

(2017/C 102/01)

([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
2017 2 13	LIFMIOR	etanerceptas	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/16/1165	Milteliai ir tirpiklis injekciniam tirpalui	L04AB01	2017 2 15
2017 2 13	Olumiant	baricitinibas	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/16/1170	Plėvele dengta tabletė	L04AA37	2017 2 15
2017 2 13	Vihuma	simoktokog alfa	Octapharma AB Lars Forssells gata 23, 112 75 Stockholm, Sverige	ES/1/16/1168	Milteliai ir tirpiklis injekciniam tirpalui	B02BD02	2017 2 15
2017 2 16	Alecensa	alektinibas	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/16/1169	Kieta kapsulė	L01XE36	2017 2 20
2017 2 17	Truxima	rituksimabas	Celltrion Healthcare Hungary Kft. 1051 Budapest Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	ES/1/16/1167	Koncentratas infuziniam tirpalui	L01XC02	2017 2 22
2017 2 27	Pregabalin Zentiva k.s	pregabalinas	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	ES/1/16/1166	Kieta kapsulė	N03AX16	2017 3 1

— **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
2017 2 6	Alimta	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/04/290	2017 2 8
2017 2 6	Amyvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/12/805	2017 2 8
2017 2 6	APTIVUS	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/05/315	2017 2 8
2017 2 6	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/06/357	2017 2 8
2017 2 6	Imvanex	Bavarian Nordic A/S Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark	ES/1/13/855	2017 2 8
2017 2 6	Scintimun	CIS bio international Boîte postale 32, F-91192 Gif-sur-Yvette, France	ES/1/09/602	2017 2 8
2017 2 6	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/06/358	2017 2 8
2017 2 6	Stribild	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/13/830	2017 2 8
2017 2 6	Tolucombi	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/13/821	2017 2 9
2017 2 6	Victrelis	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/11/704	2017 2 8
2017 2 8	Optruma	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/98/074	2017 2 10
2017 2 13	Aripiprazole Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	ES/1/15/1009	2017 2 15
2017 2 13	Senshio	Shionogi Limited 33 Kingsway, London WC2B 6UF, United Kingdom	ES/1/14/978	2017 2 15
2017 2 13	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/99/110	2017 2 15
2017 2 16	Aripiprazole Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	ES/1/15/1029	2017 2 20

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 2 16	Armisarte	Actavis Group PTC ehf. Reykjavíkurvegi 76–78, 220 Hafnarfjörður, Íceland	ES/1/15/1063	2017 2 20
2017 2 16	Brimica Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/14/963	2017 2 20
2017 2 16	Docetaxel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/09/611	2017 2 20
2017 2 16	Duaklir Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/14/964	2017 2 20
2017 2 16	Enyglid	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/09/580	2017 2 20
2017 2 16	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/15/1025	2017 2 20
2017 2 16	Farydak	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/15/1023	2017 2 20
2017 2 16	Forsteo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/03/247	2017 2 20
2017 2 16	Genvoya	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/15/1061	2017 2 20
2017 2 16	INOmax	Linde Healthcare AB SE-181 81 Lidingö, Sverige	ES/1/01/194	2017 2 22
2017 2 16	Irbesartan/Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/09/583	2017 2 20
2017 2 16	Kadcyla	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/13/885	2017 2 20
2017 2 16	Kalydeco	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	ES/1/12/782	2017 2 20
2017 2 16	Leganto	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	ES/1/11/695	2017 2 20
2017 2 16	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/97/051	2017 2 20
2017 2 16	Neupro	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	ES/1/05/331	2017 2 20

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 2 16	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/12/767	2017 2 20
2017 2 16	Nonafact	Sanquin Plasma Products B.V. Plesmanlaan 125, NL-1066 CX Amsterdam, Nederland	ES/1/01/186	2017 2 20
2017 2 16	Nucala	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	ES/1/15/1043	2017 2 20
2017 2 16	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	ES/1/07/398	2017 2 20
2017 2 16	Portrazza	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/15/1084	2017 2 20
2017 2 16	Quinsair	Horizon Pharma Europe B.V. Naritaweg 165, NL-1043 BW Amsterdam, Nederland	ES/1/14/973	2017 2 20
2017 2 16	Ravicti	Horizon Pharma Ireland Limited Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland	ES/1/15/1062	2017 2 20
2017 2 16	Repaglinide Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/09/579	2017 2 20
2017 2 16	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	ES/1/07/391	2017 2 20
2017 2 16	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/10/612	2017 2 20
2017 2 16	Rivastigmine Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76–78, 220 Hafnarfjörður, Ísland	ES/1/11/693	2017 2 20
2017 2 16	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/97/050	2017 2 20
2017 2 16	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/99/111	2017 2 20
2017 2 16	Twynsta	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/10/648	2017 2 20
2017 2 16	Viread	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/01/200	2017 2 20

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 2 16	Zyprexa Velotab	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/99/125	2017 2 20
2017 2 17	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	ES/1/11/749	2017 2 21
2017 2 17	Cyramza	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/14/957	2017 2 21
2017 2 17	Emend	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/03/262	2017 2 21
2017 2 17	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/14/945	2017 2 21
2017 2 17	Pioglitazone Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/12/757	2017 2 21
2017 2 17	Pioglitazone Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/12/758	2017 2 21
2017 2 17	Repatha	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	ES/1/15/1016	2017 2 21
2017 2 23	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/12/792	2017 2 27
2017 2 23	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/14/939	2017 2 27
2017 2 23	Docetaxel Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/12/769	2017 2 27
2017 2 23	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	ES/1/12/770	2017 2 27
2017 2 23	Exviera	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	ES/1/14/983	2017 2 27
2017 2 23	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/14/958	2017 2 27
2017 2 23	Ilaris	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/09/564	2017 2 27

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 2 23	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	ES/1/14/965	2017 2 27
2017 2 23	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/09/566	2017 2 27
2017 2 23	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/14/924	2017 2 27
2017 2 23	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	ES/1/07/391	2017 2 27
2017 2 23	Sovaldi	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/13/894	2017 2 27
2017 2 23	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	ES/1/13/892	2017 2 27
2017 2 23	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/14/954	2017 2 27
2017 2 23	Viekirax	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	ES/1/14/982	2017 2 27
2017 2 23	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/12/785	2017 2 27
2017 2 27	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/08/476	2017 3 1
2017 2 27	Kisplyx	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	ES/1/16/1128	2017 3 1
2017 2 27	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	ES/1/07/423	2017 3 1

— **Rinkodaros leidimo suteikimas** (Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004 38 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
2017 2 2	VarroMed	oksalo rūgšties dihidratas/skruzdžių rūgštis	BeeVital GmbH Wiesenbergstrasse 19, 5164, Seeham, Österreich	ES/2/16/203	Avilio dispersija	Pending	2017 2 6
2017 2 9	Stronghold Plus	Selamektinas/sarolaneras	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/16/204	Užlašinamasis tirpalas	QP54AA55	2017 2 13

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Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 2 9	EQUIOXX	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	ES/2/08/083	2017 2 13
2017 2 10	Vectormune ND	CEVA-Phylaxia Co. Ltd. Budapest, Szállás u. 5, 1107 MAGYARORSZÁG	ES/2/15/188	2017 2 14
2017 2 17	ERYSENG PARVO	Laboratorios Hipra, S.A. Avda. La Selva, 135, E-17170- Amer (Girona), España	ES/2/14/167	2017 2 21
2017 2 17	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	ES/2/13/155	2017 2 21
2017 2 17	Vectra 3D	CEVA SANTE ANIMALE 10 avenue de la Ballastière, F-33500 Libourne, France	ES/2/13/156	2017 2 21
2017 2 27	Equip WNV	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/08/086	2017 3 1

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

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom