IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2016 m. gruodžio 1 d. iki 2016 m. gruodžio 31 d.

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

(2017/C 028/01)

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([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
2016 12 5	Venclyxto	Venetoklaksas	AbbVie Ltd Vanwall Road, Maidenhead, SL6 4UB, United Kingdom	ES/1/16/1138	Plėvele dengta tabletė	L01X	2016 12 7
2016 12 8	Emtricitabine/Tenofovir disoproxil Krka	emtricitabinas/tenofoviras dizoproksilis	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/16/1151	Plėvele dengta tabletė	J05AR03	2016 12 12
2016 12 8	SomaKit TOC	edotreotidas	Advanced Accelerator Applications 20 rue Diesel, F-1630 Saint-Genis-Pouilly, France	ES/1/16/1141	Milteliai injekciniam tirpalui	V09IX09	2016 12 12
2016 12 8	Tenofovir disoproxil Mylan	Tenofoviro dizoproksilio	MYLAN S.A.S 117 Allée des Parcs, 69800 Saint-Priest, France	ES/1/16/1129	Plėvele dengta tabletė	J05AF07	2016 12 12
2016 12 12	OCALIVA	obeticholio rūgšties	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	ES/1/16/1139	Plėvele dengta tabletė	A05AA04	2016 12 15
2016 12 12	Rekovelle	folitropino delta	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 Copenhagen S, Danmark	ES/1/16/1150		G03GA10	2016 12 14
2016 12 16	Emtricitabine/Tenofovir disoproxil Mylan	emtricitabinas/tenofoviras dizoproksilis	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	ES/1/16/1133	Plėvele dengta tabletė	J05AR03	2016 12 20

— **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
2016 12 2	Aclasta	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/05/308	2016 12 6
2016 12 5	Pioglitazone Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/11/722	2016 12 7
2016 12 5	Spedra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	ES/1/13/841	2016 12 7
2016 12 5	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	ES/1/16/1126	2016 12 7
2016 12 8	Actraphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	ES/1/02/229	2016 12 12
2016 12 8	Actrapid	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	ES/1/02/230	2016 12 12
2016 12 8	Adenuric	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	ES/1/08/447	2016 12 12
2016 12 8	Bosulif	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/13/818	2016 12 12
2016 12 8	CONTROLOC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	ES/1/09/515	2016 12 12
2016 12 8	Cystadane	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	ES/1/06/379	2016 12 12
2016 12 8	DuoPlavin	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	ES/1/10/619	2016 12 12
2016 12 8	Eperzan	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	ES/1/13/908	2016 12 14
2016 12 8	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/11/677	2016 12 12

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 12 8	Holoclar	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	ES/1/14/987	2016 12 12
2016 12 8	Icandra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/484	2016 12 12
2016 12 8	Lamivudine/Zidovudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/10/663	2016 12 12
2016 12 8	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	ES/1/04/292	2016 12 5
2016 12 8	Otezla	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	ES/1/14/981	2016 12 12
2016 12 8	PANTOZOL Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	ES/1/09/517	2016 12 12
2016 12 8	SOMAC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	ES/1/09/516	2016 12 12
2016 12 8	Voriconazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/13/835	2016 12 12
2016 12 8	Zebinix	Bial – Portela & C[a], SA À Av. da Siderurgia Nacional 4745–457 S. Mamede do Coronado, Portugal	ES/1/09/514	2016 12 12
2016 12 8	Zoledronic acid Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76–78, 220 Hafnarfjörður, Íceland	ES/1/12/759	2016 12 12
2016 12 9	Ecansya	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/12/763	2016 12 12
2016 12 12	Accofil	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/14/946	2016 12 14
2016 12 12	Aldara	MEDA AB Pipers väg 2A, SE-170 73 Solna, Sverige	ES/1/98/080	2016 12 14
2016 12 12	Aripiprazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/15/1045	2016 12 14

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 12 12	Colobreathe	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/11/747	2016 12 14
2016 12 12	Cometriq	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	ES/1/13/890	2016 12 14
2016 12 12	Competact	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/06/354	2016 12 14
2016 12 12	Crixivan	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/96/024	2016 12 14
2016 12 12	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	ES/1/12/770	2016 12 15
2016 12 12	Ebymect	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/15/1051	2016 12 14
2016 12 12	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/457	2016 12 14
2016 12 12	Eucreas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/425	2016 12 14
2016 12 12	Flebogamma DIF	Instituto Grifols, S.A. Can Guasch 2, Parets del Vallès, E-08150 Barcelona, Espaňa	ES/1/07/404	2016 12 14
2016 12 12	Glubrava	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/07/421	2016 12 14
2016 12 12	Humira	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	ES/1/03/256	2016 12 14
2016 12 12	Inflectra	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	ES/1/13/854	2016 12 14
2016 12 12	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/455	2016 12 14
2016 12 12	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/12/780	2016 12 14
2016 12 12	Komboglyze	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/11/731	2016 12 14
2016 12 12	Kyprolis	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	ES/1/15/1060	2016 12 14
2016 12 12	Lynparza	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/14/959	2016 12 14

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 12 12	Mysimba	Orexigen Therapeutics Ireland Limited 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland	ES/1/14/988	2016 12 14
2016 12 12	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/12/767	2016 12 14
2016 12 12	NovoMix	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	ES/1/00/142	2016 12 14
2016 12 12	Optaflu	Seqirus GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland	ES/1/07/394	2016 12 14
2016 12 12	Orbactiv	The Medicines Company UK Ltd 115L Milton Park, Abingdon, Oxfordshire OX14 4SA, United Kingdom	ES/1/15/989	2016 12 14
2016 12 12	Pregabalin Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/15/1027	2016 12 14
2016 12 12	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/10/620	2016 12 14
2016 12 12	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/15/1003	2016 12 14
2016 12 12	TAGRISSO	AstraZeneca AB Gärtunavägen, SE-151 85 Södertälje, Sverige	ES/1/16/1086	2016 12 14
2016 12 12	Trulicity	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/14/956	2016 12 14
2016 12 12	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/456	2016 12 14
2016 12 12	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	ES/1/08/470	2016 12 14
2016 12 12	Vipdomet	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/13/843	2016 12 14
2016 12 12	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/14/918	2016 12 14
2016 12 12	Xigduo	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/13/900	2016 12 14

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 12 12	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	ES/1/13/846	2016 12 14
2016 12 12	Zomarist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/483	2016 12 14
2016 12 13	GONAL-f	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	ES/1/95/001	2016 12 16
2016 12 16	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	ES/1/07/430	2016 12 21
2016 12 16	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	ES/1/11/749	2016 12 20
2016 12 16	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, Northern Ireland BT51 3 RP, United Kindom	ES/1/03/270	2016 12 20
2016 12 16	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	ES/1/04/278	2016 12 20
2016 12 16	Mixtard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	ES/1/02/231	2016 12 20
2016 12 16	Pemetrexed Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/15/1034	2016 12 20
2016 12 16	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/08/490	2016 12 20
2016 12 16	RotaTeq	Sanofi Pasteur MSD SAS 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/06/348	2016 12 20
2016 12 16	Sebivo	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/388	2016 12 20
2016 12 19	Entyvio	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/14/923	2016 12 21
2016 12 19	Pemetrexed Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	ES/1/15/1037	2016 12 21
2016 12 19	Tractocile	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 Copenhagen S, Danmark	ES/1/99/124	2016 12 21
2016 12 19	Visudyne	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/00/140	2016 12 21

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 12 23	Duloxetine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	ES/1/15/1010	2017 1 5
2016 12 23	Fareston	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	ES/1/96/004	2017 1 4
2016 12 23	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/96/026	2017 1 4
2016 12 23	Mepact	Takeda France SAS Immeuble Pacific, 11–13 cours Valmy, 92800 Puteaux, France	ES/1/08/502	2017 1 4
2016 12 23	Orkambi	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	ES/1/15/1059	2017 1 4
2016 12 23	Raplixa	Mallinckrodt Pharmaceuticals Ireland Limited College Business & Technology Park Cruiserath, Blanchardstown, Dublin 15, Ireland	ES/1/14/985	2017 1 4
2016 12 23	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/13/901	2017 1 4

— **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
2016 12 16	Budesonide/Formoterol Teva	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	ES/1/14/948	2016 12 20
2016 12 16	Budesonide/Formoterol Teva Pharma B.V.	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	ES/1/14/950	2016 12 20

— **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
2016 12 13	Cepedex	deksmedetomidinas	CP Pharma Handelsgesellschaft mbH Ostlandring 13, D-31303 Burgdorf, Deutschland	ES/2/16/200	Injekcinis tirpalas	QN05CM18	2016 12 15
2016 12 13	Halagon	halofuginonas	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	ES/2/16/201	Geriamasis tirpalas	QP51AX08	2016 12 15

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

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 12 13	Parvoduk	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	ES/2/14/162	2016 12 15
2016 12 13	Zulvac 1 + 8 Bovis	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/12/139	2016 12 15
2016 12 14	Activyl Tick Plus	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	ES/2/11/137	2016 12 16
2016 12 14	Porcilis PCV M Hyo	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	ES/2/14/175	2016 12 16
2016 12 14	Versican Plus DHPPi	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/14/169	2016 12 16
2016 12 14	Versican Plus DHPPi/L4	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/14/164	2016 12 16
2016 12 14	Versican Plus DHPPi/L4R	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/14/163	2016 12 16

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

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