IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2015 m. gruodžio 1 d. iki 2015 m. gruodžio 31 d.

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

(2016/C 035/01)

([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
2015 12 2	Ciambra	Pemetreksedo	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	ES/1/15/1055	Milteliai koncentratui infuziniam tirpalui	L01BA04	2015 12 4
2015 12 2	Nucala	Mepolizumabas	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	ES/1/15/1043	Milteliai injekciniam tirpalui	Pending	2015 12 7
2015 12 16	Imlygic	Talimogenas laherparepvekas	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	ES/1/15/1064	Injekcinis tirpalas	Pending	2015 12 18

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

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2015 12 21	Heparesc	Cytonet GmbH & Co. KG Albert-Ludwig-Grimm Straße 20, D-69469 Weinheim, Deutschland	—	2015 12 23

— **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
2015 12 2	Tadalafil Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	ES/1/14/961	2015 12 4
2015 12 2	Twinrix Adult	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	ES/1/96/020	2015 12 4
2015 12 2	Twinrix Paediatric	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	ES/1/97/029	2015 12 4
2015 12 2	Zyclara	MEDA AB Pipers väg 2A, SE-170 73 Solna, Sverige	ES/1/12/783	2015 12 4
2015 12 9	Abasaglar	Eli Lilly Regional Operations GmbH. Kölblgasse 8–10, 1030 Wien, Österreich	ES/1/14/944	2015 12 11
2015 12 9	Voriconazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/13/835	2015 12 11
2015 12 10	Accofil	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/14/946	2015 12 14
2015 12 10	Amyvid	Eli Lilly Nederland B.V. Grootslag 1–5, NL-3991 RA Houten, Nederland	ES/1/12/805	2015 12 14
2015 12 10	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	ES/1/07/419	2015 12 14
2015 12 10	Efient	DAIICHI SANKYO EUROPE GmbH Zielstattstrasse 48, D-81379 München, Deutschland	ES/1/08/503	2015 12 14
2015 12 10	Gardasil	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/06/357	2015 12 14
2015 12 10	Holoclar	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	ES/1/14/987	2015 12 14

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2015 12 10	Ifirmasta	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/08/480	2015 12 14
2015 12 10	Remsima	Celltrion Healthcare Hungary Kft. Árpád Fejedelem útja 26–28, H-1023 Budapest, Magyarország	ES/1/13/853	2015 12 14
2015 12 10	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/06/358	2015 12 14
2015 12 10	Starlix	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/01/174	2015 12 14
2015 12 10	Synagis	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	ES/1/99/117	2015 12 14
2015 12 10	Vipidia	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/13/844	2015 12 14
2015 12 10	Votubia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/11/710	2015 12 14
2015 12 10	Zoledronic acid Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76–78, 220 Hafnarfjörður, Ísland	ES/1/12/759	2015 12 14
2015 12 14	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	ES/1/07/430	2015 12 16
2015 12 14	Envarsus	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	ES/1/14/935	2015 12 16
2015 12 14	Incruse	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	ES/1/14/922	2015 12 16
2015 12 14	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	ES/1/14/930	2015 12 16
2015 12 14	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	ES/1/08/452	2015 12 16
2015 12 14	Yervoy	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/11/698	2015 12 16
2015 12 16	Aldurazyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	ES/1/03/253	2015 12 18
2015 12 16	Angiox	The Medicines Company UK Ltd 115L Milton Park, Abingdon, Oxfordshire OX14 4SA, United Kingdom	ES/1/04/289	2015 12 18
2015 12 16	AUBAGIO	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	ES/1/13/838	2015 12 18

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2015 12 16	BYDUREON	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/11/696	2015 12 18
2015 12 16	Byetta	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/06/362	2015 12 18
2015 12 16	Caprelsa	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/11/749	2015 12 18
2015 12 16	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	ES/1/03/268	2015 12 18
2015 12 16	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	ES/1/09/544	2015 12 18
2015 12 16	Emend	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/03/262	2015 12 18
2015 12 16	Eucreas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/425	2015 12 18
2015 12 16	Fuzeon	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/03/252	2015 12 18
2015 12 16	Galvus	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/414	2015 12 18
2015 12 16	Icandra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/484	2015 12 18
2015 12 16	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/13/884	2015 12 18
2015 12 16	Jalra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/485	2015 12 18
2015 12 16	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, Northern Ireland BT51 3 RP, United Kindom	ES/1/03/270	2015 12 21
2015 12 16	Lyrica	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/04/279	2015 12 18
2015 12 16	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/12/767	2015 12 18
2015 12 16	ProQuad	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/05/323	2015 12 18
2015 12 16	Protopic	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	ES/1/02/201	2015 12 18

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2015 12 16	Stivarga	Bayer Pharma AG D-13342 Berlin, Deutschland	ES/1/13/858	2015 12 18
2015 12 16	Tecfidera	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	ES/1/13/837	2015 12 22
2015 12 16	Vfend	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/02/212	2015 12 18
2015 12 16	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/14/918	2015 12 18
2015 12 16	Xeplion	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/11/672	2015 12 18
2015 12 16	Xiliarx	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/486	2015 12 18
2015 12 16	Zomarist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/483	2015 12 18
2015 12 16	Zutectra	Biotest Pharma GmbH Landsteinerstrasse 5, D-63303 Dreieich, Deutschland	ES/1/09/600	2015 12 18
2015 12 18	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/14/958	2015 12 22
2015 12 18	Zostavax	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/06/341	2015 12 22

— **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
2015 12 16	Osigraft	Olympus Biotech International Limited 40 Upper Mount Street, Dublin 2, Ireland	ES/1/01/179	2015 12 21

— **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
2015 12 9	Imrestor	pegbovigrastimas	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	ES/2/15/193	Injekcinis tirpalas	QL03AA90	2015 12 11
2015 12 9	Velactis	Kabergolinas	Ceva Santé Animale 10 av. de La Ballastière, 33500 Libourne, France	ES/2/15/192	Injekcinis tirpalas	QG02CB03	2015 12 11

— **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
2015 12 2	Easotic	VIRBAC S.A. 1ère Avenue – 2065 m – L.I.D., F-06516 Carros CEDEX, France	ES/2/08/085	2015 12 4
2015 12 2	Inflacam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	ES/2/11/134	2015 12 4
2015 12 2	Purevax Rabies	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	ES/2/10/117	2015 12 4
2015 12 18	Equip WNV	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	ES/2/08/086	2015 12 21
2015 12 18	Novem	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	ES/2/04/042	2015 12 22
2015 12 18	Purevax RC	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	ES/2/04/051	2015 12 22

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

The European Medicines Agency
7, Westferry Circus, Canary Wharf
UK – LONDON E14 4H