IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2016 m. birželio 1 d. iki 2016 m. birželio 30 d.

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

(2016/C 277/01)

([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
2016 6 21	Odefsey	emtricitabinas/rilpivirinas/tenofoviro alafenamidas	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/16/1112	Plėvele dengta tabletė	J05AR19	2016 6 23
2016 6 24	Ongentys	opikaponas	Bial – Portela & C[a], SA À Av. da Siderurgia Nacional 4745–457 S. Mamede do Coronado, Portugal	ES/1/15/1066	Kieta kapsulė	Pending	2016 6 28
2016 6 24	Zavicefta	ceftazidimas/avibaktamas	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/16/1109	Milteliai koncentratui infuziniam tirpalui	J01DD52	2016 6 28
2016 6 29	Enzepi	Kasos milteliai	APTALIS PHARMA SAS 5/6 Place de l'Iris – La Défense 5 92400 Courbevoie France	ES/1/16/1113	Kietos skrandžio sultims atsparios kapsulė	A09AA02	2016 7 1

— **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
2016 6 24	Dropcys	Lucane Pharma 172 rue de Charonne, 75011 Paris, France		2016 6 28

— **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 6 1	Cotellic	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/15/1048	2016 6 3
2016 6 1	HyQvia	Baxalta Innovations GmbH Industriestrasse 67, A-1221 Wien, Österreich	ES/1/13/840	2016 6 6
2016 6 1	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	ES/1/07/391	2016 6 3
2016 6 1	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	ES/1/12/785	2016 6 3
2016 6 2	Adrovance	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/06/364	2016 6 6
2016 6 2	Altargo	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	ES/1/07/390	2016 6 6
2016 6 2	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/04/300	2016 6 6
2016 6 2	Capecitabine Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/12/762	2016 6 6
2016 6 2	Clopidogrel BGR	Laboratoires BIOGARAN 15 boulevard Charles de Gaulle, 92707 Colombes Cedex, France	ES/1/09/558	2016 6 6
2016 6 2	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/09/556	2016 6 7
2016 6 2	Clopidogrel ratiopharm GmbH	Archie Samuel s.r.o. Slunná 16, CZ-61700 Brno, Česká republika	ES/1/09/541	2016 6 6

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 6 2	Imatinib Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76–78, 220 Hafnarfjörður, Ísland	ES/1/13/825	2016 6 6
2016 6 2	Kineret	Swedish Orphan Biovitrum AB (publ) SE-112 76 Stockholm, Sverige	ES/1/02/203	2016 6 7
2016 6 2	Kiovig	Baxter AG Industriestrasse 67, A-1221 Wien, Österreich	ES/1/05/329	2016 6 6
2016 6 2	Lonquex	UAB „Sicor Biotech“ Molėtų pl. 5, LT-08409 Vilnius, Lietuva	ES/1/13/856	2016 6 6
2016 6 2	Neuraceq	Piramal Imaging Limited Langstone Technology Park, Langstone Road, Havant, Hampshire, PO9 1SA, United Kingdom	ES/1/13/906	2016 6 6
2016 6 2	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/422	2016 6 6
2016 6 2	Temozolomide Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	ES/1/10/615	2016 6 6
2016 6 2	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	ES/1/08/470	2016 6 6
2016 6 9	Cubicin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/05/328	2016 6 13
2016 6 9	Telmisartan Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/11/719	2016 6 13
2016 6 9	VPRIV	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	ES/1/10/646	2016 6 13
2016 6 9	Zyllt	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/09/553	2016 6 13
2016 6 13	Gazyvaro	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/14/937	2016 6 15
2016 6 16	Advagraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	ES/1/07/387	2016 6 20
2016 6 16	Avonex	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	ES/1/97/033	2016 6 20

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 6 16	Protopic	Leo Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	ES/1/02/201	2016 6 20
2016 6 16	Tesavel	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/07/435	2016 6 20
2016 6 16	Xelevia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/07/382	2016 6 20
2016 6 21	Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A Viale Shakespeare 47, 00144 Roma, Italia	ES/1/11/716	2016 6 23
2016 6 21	Irbesartan Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	ES/1/06/376	2016 6 23
2016 6 21	Karvea	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	ES/1/97/049	2016 6 23
2016 6 21	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	ES/1/13/869	2016 6 23
2016 6 21	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	ES/1/09/523	2016 6 23
2016 6 21	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/03/267	2016 6 23
2016 6 21	Zometa	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/01/176	2016 6 23
2016 6 24	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/12/794	2016 6 28
2016 6 24	Advate	Baxter AG Industriestrasse 67, A-1221 Wien, Österreich	ES/1/03/271	2016 6 28
2016 6 24	Aprovel	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	ES/1/97/046	2016 6 28
2016 6 24	Cubicin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/05/328	2016 6 28
2016 6 24	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/14/939	2016 6 28

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 6 24	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/03/261	2016 6 28
2016 6 24	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	ES/1/09/535	2016 6 28
2016 6 24	Humira	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	ES/1/03/256	2016 6 28
2016 6 24	Imnovid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	ES/1/13/850	2016 6 28
2016 6 24	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/07/383	2016 6 28
2016 6 24	Rasilez	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/405	2016 6 28
2016 6 24	Rasilez HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/08/491	2016 6 28
2016 6 24	Relvar Ellipta	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	ES/1/13/886	2016 6 28
2016 6 24	Revinty Ellipta	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	ES/1/14/929	2016 6 28
2016 6 24	Simponi	Janssen Biologics B.V. Einsteinweg 101, NL-2333 CB Leiden, Nederland	ES/1/09/546	2016 6 28
2016 6 24	Tolura	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	ES/1/10/632	2016 6 28
2016 6 24	Tysabri	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	ES/1/06/346	2016 6 28
2016 6 24	Zoledronic acid Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	ES/1/12/800	2016 6 28
2016 6 29	Champix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/06/360	2016 7 1

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 6 29	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/11/720	2016 7 1
2016 6 29	Kivexa	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	ES/1/04/298	2016 7 1
2016 6 29	Kyprolis	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	ES/1/15/1060	2016 7 1
2016 6 29	Matever	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	ES/1/11/711	2016 7 1
2016 6 29	Memantine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	ES/1/13/827	2016 7 8
2016 6 29	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	ES/1/08/448	2016 7 1
2016 6 29	PegIntron	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/00/131	2016 7 1
2016 6 29	Revestive	NPS Pharma Holdings Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	ES/1/12/787	2016 7 1
2016 6 29	Tyverb	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/07/440	2016 7 1
2016 6 29	Vidaza	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom	ES/1/08/488	2016 7 1
2016 6 29	ViraferonPeg	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/00/132	2016 7 4
2016 6 29	Yondelis	Pharma Mar S.A. Avda de los Reyes 1, Polígono Industrial La Mina, E-28770 Colmenar Viejo, Madrid, España	ES/1/07/417	2016 7 1
2016 6 29	Zoledrono rūgštis medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6, D-22880 Wedel, Deutschland	ES/1/12/779	2016 7 1
2016 6 30	Ceplene	MEDA AB Box 906, SE-170 09 Solna, Sverige	ES/1/08/477	2016 7 5
2016 6 30	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/12/792	2016 7 4

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2016 6 30	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/457	2016 7 4
2016 6 30	Eylea	Bayer Pharma AG D-13342 Berlin, Deutschland	ES/1/12/797	2016 7 4
2016 6 30	Filgrastim Hexal	Hexal AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	ES/1/08/496	2016 7 4
2016 6 30	Hycamtin	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/96/027	2016 7 4
2016 6 30	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/455	2016 7 4
2016 6 30	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	ES/1/14/924	2016 7 4
2016 6 30	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/10/621	2016 7 4
2016 6 30	Toujeo	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	ES/1/00/133	2016 7 4
2016 6 30	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/456	2016 7 4
2016 6 30	Yentreve	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/04/280	2016 7 4
2016 6 30	Zarzio	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	ES/1/08/495	2016 7 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 6 1	Clopidogrel/Acetyl-salicylic acid Teva	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	ES/1/14/942	2016 6 3
2016 6 21	Capecitabine SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland	ES/1/13/831	2016 6 23
2016 6 30	Krystexxa	Crealta Pharmaceuticals Ireland Limited Commercial House, Millbank Business Park, Lower Lucan Road, Lucan, Co.Dublin, Ireland	ES/1/12/810	2016 7 4
2016 6 30	Opgenra	Olympus Biotech International Limited 40 Upper Mount Street, Dublin 2, Ireland	ES/1/08/489	2016 7 4

— **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 6 21	Sevocalm	sevofluranas	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	ES/2/16/196	Inhaliaciniai garai, skystis	Pending	2016 6 24

— **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 6 3	Nobivac L4	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	ES/2/12/143	2016 6 7
2016 6 21	Emdocam	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	ES/2/11/128	2016 6 23
2016 6 21	Metacam	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	ES/2/97/004	2016 6 23
2016 6 22	Nobilis Influenza H5N2	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	ES/2/06/061	2016 6 24
2016 6 24	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	ES/2/08/090	2016 6 29

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