IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

Europos Sąjungos sprendimų dėl vaistų rinkodaros leidimų santrauka nuo 2017 m. gruodžio 1 d. iki 2017 m. gruodžio 31 d.

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

(2018/C 030/01)

([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 12 8	Tacforius	Takrolimuzas	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/17/1244	Pailginto atpalaidavimo kietos kapsulės	L04AD02	2017 12 12
2017 12 18	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 12 20

— **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
2017 12 8	Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech	XBiotech Germany GmbH Lyoner Straße 14, 60528 Frankfurt am Main, Deutschland	—	2017 12 12
2017 12 18	Masipro	AB Science 3 avenue George V, 75008 Paris, France	—	2017 12 20

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Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 12 1	Alecensa	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/16/1169	2017 12 5
2017 12 1	Hetlioz	Vanda Pharmaceuticals Limited 25 Old Broad Street, level 21a, London EC2N 1HQ, United Kingdom	ES/1/15/1008	2017 12 5
2017 12 1	Jakavi	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/12/773	2017 12 5
2017 12 1	OCALIVA	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	ES/1/16/1139	2017 12 5
2017 12 1	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	ES/1/08/498	2017 12 5
2017 12 8	Ceplene	Noventia Pharma Srl Via Carlo Pisacane 31, 47121 Forli, Italia	ES/1/08/477	2017 12 12
2017 12 8	Dexdor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	ES/1/11/718	2017 12 12
2017 12 8	Esbriet	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/11/667	2017 12 13
2017 12 8	Esmya	Gedeon Richter Plc. Gyömrői út 19–21., 1103 Budapest, Magyarország	ES/1/12/750	2017 12 12

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 12 8	Genvoya	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/15/1061	2017 12 12
2017 12 8	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	ES/1/11/677	2017 12 13
2017 12 8	Humira	AbbVie Ltd Abbvie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4UB, United Kingdom	ES/1/03/256	2017 12 12
2017 12 8	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/07/383	2017 12 13
2017 12 8	JETREA	ThromboGenics NV Gaston Geenslaan 1, 3001 Leuven, België	ES/1/13/819	2017 12 12
2017 12 8	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/15/1024	2017 12 13
2017 12 8	Leganto	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	ES/1/11/695	2017 12 12
2017 12 8	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	ES/1/13/869	2017 12 13
2017 12 8	Moventig	Kyowa Kirin Limited Galabank Business Park, Galashiels, TD1 1QH, United Kingdom	ES/1/14/962	2017 12 12
2017 12 8	Mysimba	Orexigen Therapeutics Ireland Limited 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland	ES/1/14/988	2017 12 12
2017 12 8	Oncaspar	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	ES/1/15/1070	2017 12 14
2017 12 8	Perjeta	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/13/813	2017 12 13
2017 12 8	Selincro	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	ES/1/12/815	2017 12 12
2017 12 8	Taltz	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/15/1085	2017 12 12

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 12 8	Tesavel	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/07/435	2017 12 13
2017 12 8	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	ES/1/16/1126	2017 12 12
2017 12 8	Xiapex	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	ES/1/11/671	2017 12 12
2017 12 8	Zevalin	Spectrum Pharmaceuticals B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	ES/1/03/264	2017 12 12
2017 12 11	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/15/1025	2017 12 13
2017 12 11	Holoclar	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	ES/1/14/987	2017 12 13
2017 12 11	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	ES/1/05/331	2017 12 13
2017 12 11	Odefsey	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/16/1112	2017 12 13
2017 12 11	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	ES/1/10/643	2017 12 15
2017 12 11	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/03/267	2017 12 13
2017 12 11	Strensiq	Alexion Europe SAS 1–15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	ES/1/15/1015	2017 12 13
2017 12 11	Tarceva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	ES/1/05/311	2017 12 13
2017 12 11	Zyclara	MEDA AB Pipers väg 2A, 170 73 Solna, Sverige	ES/1/12/783	2017 12 13

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 12 15	Actelsar HCT	Actavis Group PTC ehf. Reykjavíkurvegi 76–78, 220 Hafnarfjörður, Íceland	ES/1/13/817	2017 12 19
2017 12 15	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/12/794	2017 12 19
2017 12 15	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/457	2017 12 19
2017 12 15	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	ES/1/11/737	2017 12 19
2017 12 15	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/455	2017 12 19
2017 12 15	M-M-RVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/06/337	2017 12 19
2017 12 15	Procysbi	Chiesi Orphan B.V. Graadt van Roggenweg 340, 3531 AH Utrecht, Nederland	ES/1/13/861	2017 12 19
2017 12 15	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/10/621	2017 12 19
2017 12 15	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/10/620	2017 12 19
2017 12 15	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/99/111	2017 12 19
2017 12 15	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/99/110	2017 12 19
2017 12 15	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/08/456	2017 12 19
2017 12 18	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	ES/1/14/939	2017 12 20
2017 12 18	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	ES/1/99/126	2017 12 20

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 12 18	HBVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/01/183	2017 12 20
2017 12 18	NovoMix	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	ES/1/00/142	2017 12 20
2017 12 18	ProQuad	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/05/323	2017 12 20
2017 12 18	Xelevia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	ES/1/07/382	2017 12 20
2017 12 20	Azilect	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	ES/1/04/304	2017 12 22
2017 12 20	Duloxetine Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	ES/1/14/972	2017 12 22
2017 12 20	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	ES/1/15/1051	2017 12 22
2017 12 20	Efient	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	ES/1/08/503	2017 12 22
2017 12 20	Fabrazyme	Genzyme Europe B.V. Gooimeer 10, 1411 DD Naarden, Nederland	ES/1/01/188	2017 12 22
2017 12 20	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	ES/1/06/357	2017 12 22
2017 12 20	Incresync	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	ES/1/13/842	2017 12 20
2017 12 20	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	ES/1/06/368	2018 1 2
2017 12 20	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	ES/1/11/702	2017 12 22
2017 12 20	Levetiracetam SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	ES/1/11/741	2017 12 22
2017 12 20	Qtern	AstraZeneca AB 151 85 Södertälje, Sverige	ES/1/16/1108	2017 12 22
2017 12 20	Ranexa	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Grand-Duché de Luxembourg	ES/1/08/462	2017 12 22
2017 12 20	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	ES/1/13/892	2017 12 22
2017 12 20	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	ES/1/13/900	2017 12 22

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2017 12 1	Rabitec	Vakcina nuo pasiutligės (gyva, peroralinė), skirta lapėms ir usūriniams šunims	IDT Biologika GmbH Am Pharmapark, 06861 Dessau-Rosslau, Deutschland	ES/2/17/219	Geriamoji suspensija	QI07BD	2017 12 5

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Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 12 6	Kexxtone	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	ES/2/12/145	2017 12 8
2017 12 6	Spironolactone Ceva	Ceva Santé Animale 10 avenue de la Ballastière, 33500 Libourne, France	ES/2/07/074	2017 12 8
2017 12 18	Sedadex	Le Vet Beheer B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	ES/2/16/198	2017 12 20
2017 12 20	Easotic	VIRBAC S.A. 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	ES/2/08/085	2017 12 22
2017 12 20	Leucogen	Virbac 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	ES/2/09/096	2017 12 22

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

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