IV

(Pranešimai)

EUROPOS SĄJUNGOS INSTITUCIJŲ, ĮSTAIGŲ IR ORGANŲ PRANEŠIMAI

EUROPOS KOMISIJA

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

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

(2017/C 328/01)

([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 7 6	OXERVATE	Cenegerminas	Dompé farmaceutici S.p.A. Via Santa Lucia 6, 20122 Milano, Italia	EU/1/17/1197	Akių lašai, tirpalas	Pending	2017 7 10
2017 7 10	Spherox	Su matrica sujungtų autologinių žmogaus chondrocitų sferoidai	CO.DON AG Warthestraße 21, 14513 Teltow, Deutschland	EU/1/17/1181	Ląstelių implantavimo suspensija	M09AX02	2017 7 12
2017 7 13	Blitzima	rituksimabas	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1205	Koncentratas infuziniam tirpalui	L01XC02	2017 7 17
2017 7 13	Reagila	kariprazino	Gedeon Richter Plc. Gyömrői út 19-21., H-1103 Budapest, Magyarország	EU/1/17/1209	Kieta kapsulė	N05AX15	2017 7 17
2017 7 13	Ritemvia	rituksimabas	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1207	Koncentratas infuziniam tirpalui	L01XC02	2017 7 17
2017 7 13	Tuxella	rituksimabas	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1206	Koncentratas infuziniam tirpalui	L01XC02	2017 7 17
2017 7 17	Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva	efavirenzas/emtricitabinas/tenofoviras dizoproksilis	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/17/1210	Plėvele dengta tabletė	J05AR06	2017 7 19
2017 7 17	Kyntheum	brodalumabas	Leo Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/16/1155	Injekcinis tirpalas	L04AC12	2017 7 19

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2017 7 17	Trimbow	beklometazonas/formoterolis/glikopironio bromidas	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/17/1208	Suslėgtasis įkvepiamasis tirpalas	R03AL09	2017 7 19
2017 7 19	Insulin lispro Sanofi	insulinas lispro	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/17/1203	Injekcinis tirpalas	A10AB04	2017 7 21
2017 7 19	Veltassa	patiromeras	Vifor Fresenius Medical Care Renal Pharma France 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/17/1179	Milteliai geriamai suspensijai	V03AE09	2017 7 21
2017 7 26	Maviret	glekapreviras/pibrentasviras	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/17/1213	Plėvele dengta tabletė	J05AX	2017 7 28
2017 7 26	Vosevi	sofosbuviras/velpatasviras/voksilapreviras	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/17/1223	Plėvele dengta tabletė	Pending	2017 7 28
2017 7 26	Zykadia	ceritinibas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/999	Kieta kapsulė	L01XE28	2017 7 28
2017 8 22	Kisqali	ribociklibas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/17/1221	Plėvele dengta tabletė	L01XE42	2017 8 24
2017 8 22	MAVENCLAD	kladribinas	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/17/1212	Tabletės	L01BB04	2017 8 24

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 8 24	Fotivda	tivozanibas	EUSA Pharma (UK) Limited Breakspear Park, Breakspear Way, HP2 4TZ, Hemel Hempstead, United Kingdom	EU/1/17/1215	Kieta kapsulė	L01XE34	2017 8 29
2017 8 24	Imraldi	adalimumabas	Samsung Bioepis UK Limited 5th floor, Profile West, 950 Great West Road, Brentford, Middlesex TW8 9ES, United Kingdom	EU/1/17/1216	Injekcinis tirpalas	L04AB04	2017 8 29
2017 8 24	Nitisinone MendeliKABS	nitizinonas	MendeliKABS Europe Limited Office 7, Gateway 1000, Whittle Way, Stevenage, Hertfordshire, SG1 2FP, United Kingdom	EU/1/17/1217	Kieta kapsulė	A16AX04	2017 8 29

— **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 7 6	Celsentri	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/07/418	2017 7 10
2017 7 6	Clopidogrel Krka d. d.	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	2017 7 10
2017 7 6	Imlygic	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1064	2017 7 10
2017 7 6	Kivexa	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/298	2017 7 10
2017 7 6	Nexavar	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/06/342	2017 7 10
2017 7 6	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386	2017 7 10
2017 7 10	Memantine Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/880	2017 7 12
2017 7 10	Myozyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/06/333	2017 7 12
2017 7 10	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	2017 7 12
2017 7 13	Edistride	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/15/1052	2017 7 17
2017 7 13	Enurev Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/789	2017 7 17
2017 7 13	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	2017 7 17
2017 7 13	Incruse	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/922	2017 7 17
2017 7 13	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436	2017 7 17

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 7 13	Kuvan	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, Ireland	EU/1/08/481	2017 7 17
2017 7 13	Latuda	Sunovion Pharmaceuticals Europe Ltd First Floor, Southside, 97-105 Victoria Street, London SW1E 6QT, United Kingdom	EU/1/14/913	2017 7 17
2017 7 13	Lixiana	Daiichi Sankyo Europe GmbH Zielstattstrasse 48, D-81379 München, Deutschland	EU/1/15/993	2017 7 17
2017 7 13	Memantine Merz	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/12/799	2017 7 17
2017 7 13	Picato	LEO Laboratories Ltd. 285 Cashel Road, Crumlin, Dublin 12, Ireland	EU/1/12/796	2017 7 17
2017 7 13	Praxbind	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1056	2017 7 17
2017 7 13	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/424	2017 7 17
2017 7 13	Xaluprine	Nova Laboratories Limited Martin House, Gloucester Crescent, Wigston Leicester, LE18 4YL, United Kingdom	EU/1/11/727	2017 7 17
2017 7 13	Xultophy	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/14/947	2017 7 17
2017 7 13	Zalmoxis	MolMed S.p.A. Via Olgettina 58, I-20132 Milano, Italia	EU/1/16/1121	2017 7 17
2017 7 13	Zoledronic acid Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/834	2017 7 17
2017 7 14	Zinbryta	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/16/1107	2017 7 18
2017 7 17	Dinutuximab beta Apeiron	EUSA Pharma (UK) Limited Breakspear Park, Breakspear Way, HP2 4TZ, Hemel Hempstead, United Kingdom	EU/1/17/1191	2017 7 19
2017 7 17	Inhixa	Techdow Europe AB Kåbovägen 32, 75236 Uppsala, Sverige	EU/1/16/1132	2017 7 20
2017 7 17	Opsumit	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/13/893	2017 7 19

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 7 17	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/09/599	2017 7 19
2017 7 17	Thorinane	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077XX Amsterdam, Nederland	EU/1/16/1131	2017 7 19
2017 7 17	Zinforo	Pfizer Ireland Pharmaceuticals Operations Services Group, Ringaskiddy, County Cork, Ireland	EU/1/12/785	2017 7 19
2017 7 19	Clopidogrel BGR	Laboratoires BIOGARAN 15 boulevard Charles de Gaulle, 92707 Colombes Cedex, France	EU/1/09/558	2017 7 21
2017 7 19	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	2017 7 21
2017 7 19	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, D-27472 Cuxhaven, Deutschland	EU/1/09/555	2017 7 21
2017 7 19	Cuprymina	SPARKLE S.r.l. Località Cavallino, 62010 Montecosaro (MC), Italia	EU/1/12/784	2017 7 24
2017 7 19	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	2017 7 24
2017 7 19	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	2017 7 21
2017 7 19	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/958	2017 7 24
2017 7 19	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	2017 7 21
2017 7 19	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	2017 7 21
2017 7 19	Qtern	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1108	2017 7 24
2017 7 19	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Strasse 8, D-79539 Lörrach, Deutschland	EU/1/15/1020	2017 7 24
2017 7 19	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	2017 7 21
2017 7 19	Seebri Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/788	2017 7 21

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 7 19	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	2017 7 21
2017 7 19	Tracleer	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220	2017 7 21
2017 7 19	Zavesca	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/238	2017 7 21
2017 7 19	Zavicefta	Pfizer Ireland Pharmaceuticals Operations Services Group, Ringaskiddy, County Cork, Ireland	EU/1/16/1109	2017 7 24
2017 7 25	Faslodex	AstraZeneca UK Limited Charter Way, Macclesfield, Cheshire, SK10 2NA, United Kingdom	EU/1/03/269	2017 7 27
2017 7 25	Granupas	Lucane Pharma 172 rue de Charonne, 75011 Paris, France	EU/1/13/896	2017 7 27
2017 7 25	Olanzapinas Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/08/475	2017 7 31
2017 7 25	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389	2017 7 27
2017 7 25	Rivastigmine 1 A Pharma	1 A Pharma GmbH Keltenring 1 + 3, D-82041 Oberhaching, Deutschland	EU/1/09/585	2017 7 28
2017 7 25	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	2017 7 27
2017 7 25	Voncento	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/13/857	2017 7 28
2017 7 26	Aripiprazole Mylan Pharma	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/15/1005	2017 7 28
2017 7 26	Bridion	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/466	2017 7 28
2017 7 26	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	2017 7 28
2017 7 26	Oprymea	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/469	2017 7 28
2017 7 26	Tovanor Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/790	2017 7 28

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 7 26	Velphoro	Vifor Fresenius Medical Care Renal Pharma France 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/14/943	2017 7 28
2017 7 26	Votubia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/710	2017 7 28
2017 7 26	Yellox	PharmaSwiss Česká republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 Česká republika	EU/1/11/692	2017 7 28
2017 8 2	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	2017 8 4
2017 8 2	Zyllt	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553	2017 8 4
2017 8 3	Abilify	Otsuka Pharmaceutical Europe Ltd. Gallions, Wexham Springs, Framewood Road, Wexham, SL3 6PJ, United Kingdom	EU/1/04/276	2017 8 17
2017 8 3	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285	2017 8 7
2017 8 7	Colobreathe	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/747	2017 8 9
2017 8 7	Nordimet	Nordic Group B.V. Siriusdreef 22, NL-2132 WT Hoofddorp, Nederland	EU/1/16/1124	2017 8 9
2017 8 7	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	2017 8 9
2017 8 14	Exjade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/356	2017 8 17
2017 8 14	Mekinist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/14/931	2017 8 18
2017 8 14	Soliris	Alexion Europe SAS 1-15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	EU/1/07/393	2017 8 17
2017 8 14	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	2017 8 17

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 8 14	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	2017 8 17
2017 8 22	CoAprovel	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/086	2017 8 24
2017 8 22	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	EU/1/14/965	2017 8 24
2017 8 22	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	2017 8 24
2017 8 22	SonoVue	Bracco International B.V. Strawinskylaan 3051, NL-1077 ZX Amsterdam, Nederland	EU/1/01/177	2017 8 24
2017 8 22	Xarelto	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/08/472	2017 8 24
2017 8 24	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185	2017 8 28
2017 8 24	BYDUREON	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/696	2017 8 28
2017 8 24	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	2017 8 28
2017 8 24	EDURANT	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/736	2017 8 28
2017 8 24	Fluenz Tetra	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/887	2017 8 28
2017 8 24	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	2017 8 28
2017 8 24	Invega	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/07/395	2017 8 28
2017 8 24	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	2017 8 29
2017 8 24	Karvezide	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/085	2017 8 28
2017 8 24	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	2017 8 29
2017 8 24	Norvir	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/96/016	2017 8 29

Sprendimo data	Vaisto pavadinimas	Rinkodaros leidimo turėtojas	Įrašo numeris Bendrijos vaistų registre	Pranešimo data
2017 8 24	Orkambi	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/15/1059	2017 8 29
2017 8 24	Ruconest	Pharming Group N.V. Darwinweg 24, NL-2333 CR Leiden, Nederland	EU/1/10/641	2017 8 28
2017 8 24	Zoledronic acid Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/12/800	2017 8 29
2017 8 28	Constella	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/12/801	2017 8 30
2017 8 28	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416	2017 8 30
2017 8 28	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	2017 8 30
2017 8 28	Irbesartan HCT Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/06/377	2017 8 30
2017 8 28	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292	2017 8 30
2017 8 28	Rasilez HCT	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/08/491	2017 8 30

— **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
2017 7 19	Enzepi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1113	2017 7 21
2017 7 19	Repso	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/674	2017 7 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
2017 8 17	VEPURED	*E. coli* verotoksino vakcina (neaktyvus rekombinantas)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/17/214	Injekcinė suspensija	QI09AB02	2017 8 21
2017 8 18	Exzolt	fluralaner	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/17/212	Tirpalas, skirtas naudoti su geriamuoju vandeniu	QP53BE02	2017 8 22
2017 8 22	Innovax-ND-IBD	Niukaslio ligos, infekcinės bursos ligos ir Mareko ligos vakcina (gyva rekombinantinė)	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/17/213	Suspensija ir skiedikliis injekcinei suspensijai	QI01AD	2017 8 24
2017 8 24	Suvaxyn PRRS MLV	Kiaulių reprodukcinio ir kvėpavimo sindromo viruso vakcina (gyva)	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	Liofilizatas ir tirpiklis injekcinei suspensijai ruošti	QI09AD03	2017 8 28

— **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
2017 7 10	Onsior	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/08/089	2017 7 12
2017 7 14	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/14/174	2017 7 18
2017 7 14	Zolvix	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/09/101	2017 7 18
2017 7 19	Aivlosin	ECO Animal Health Ltd 78 Coombe Road, New Malden, Surrey KT3 4QS United Kingdom	EU/2/04/044	2017 7 21
2017 7 28	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090	2017 8 1
2017 7 28	Vaxxitek HVT + IBD	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/02/032	2017 8 1
2017 8 3	BLUEVAC BTV8	CZ Veterinaria, S.A. La Relva s/n, 36400 Porriño, España	EU/2/11/122	2017 8 7
2017 8 10	Canigen L4	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/15/183	2017 8 14

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

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