Eiropas Savienības
Oficiālais Vēstnesis

C 211

Izdevums latviešu valodā

Informācija un paziņojumi

58. sējums

2015. gada 26. jūnijs

Saturs

IV *Paziņojumi*

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

Eiropas Komisija

2015/C 211/01 Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2015. gada 1. maija līdz 2015. gada 31. maijam *(Publicēts saskaņā ar Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. vai 38. pantu)* 1

LV

IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2015. gada 1. maija līdz 2015. gada 31. maijam

(Publicēts saskaņā ar Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 ([1]) 13. vai 38. pantu)

(2015/C 211/01)

([1]) OV L 136, 30.4.2004., 1. lpp.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	*INN* (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
6.5.2015.	Zykadia	ceritiniba	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/999	Cietās kapsulas	L01XE	8.5.2015.
27.5.2015.	Akynzeo	Netupitant/Palonosetron	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	Cietās kapsulas	A04AA55	29.5.2015.
27.5.2015.	Jinarc	tolvaptan	Otsuka Pharmaceutical Europe Ltd. Gallions, Wexham Springs, Framewood Road, Wexham, SL3 6PJ, United Kingdom	EU/1/15/1000	Tabletes	Pending	29.5.2015.
27.5.2015.	Synjardy	empagliflozīns/metformīns	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	Apvalkotās tabletes	A10BD20	29.5.2015.
27.5.2015.	Voriconazole Hospira	Voriconazole	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/15/1004	Pulveris infūziju šķīduma pagatavošanai	J02AC03	29.5.2015.
28.5.2015.	Lenvima	lenvatinib	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/15/1002	Cietās kapsulas	L01XE29	1.6.2015.

— **Tirdzniecības atļaujas grozīšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
5.5.2015.	Copalia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/372	7.5.2015.
5.5.2015.	Copalia HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/575	7.5.2015.
5.5.2015.	Dafiro	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/371	7.5.2015.
5.5.2015.	Dafiro HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/574	7.5.2015.
5.5.2015.	Erivedge	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/848	8.5.2015.
5.5.2015.	Exforge	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/370	7.5.2015.
5.5.2015.	Exforge HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/569	7.5.2015.
5.5.2015.	Imprida	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/373	7.5.2015.
5.5.2015.	INCRELEX	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/07/402	7.5.2015.
5.5.2015.	Irbesartan/Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	8.5.2015.
5.5.2015.	Orfadin	Swedish Orphan Biovitrum International AB SE-112 76 Stockholm, Sverige	EU/1/04/303	8.5.2015.
5.5.2015.	Sycrest	Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland	EU/1/10/640	7.5.2015.
5.5.2015.	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222	8.5.2015.
5.5.2015.	Telzir	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/282	7.5.2015.
5.5.2015.	Tyverb	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/440	7.5.2015.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
5.5.2015.	Voncento	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/13/857	7.5.2015.
5.5.2015.	Votrient	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/628	7.5.2015.
5.5.2015.	Zoledronic acid Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/772	7.5.2015.
5.5.2015.	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/479	7.5.2015.
6.5.2015.	Arzerra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/625	8.5.2015.
6.5.2015.	Celsentri	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/07/418	8.5.2015.
6.5.2015.	Celvapan	Baxter AG Industriestraße 67, A-1221 Wien, Österreich	EU/1/08/506	8.5.2015.
6.5.2015.	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	8.5.2015.
6.5.2015.	Imatinib Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/808	8.5.2015.
6.5.2015.	Optaflu	Novartis Influenza Vaccines Marburg GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/07/394	8.5.2015.
6.5.2015.	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	8.5.2015.
6.5.2015.	Tafinlar	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/13/865	8.5.2015.
13.5.2015.	Cayston	Gilead Sciences International Limited Granta Park, Abington, Cambridge CB21 6GT, United Kingdom	EU/1/09/543	19.5.2015.
13.5.2015.	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	19.5.2015.
13.5.2015.	Granupas	Lucane Pharma 172 rue de Charonne, 75011 Paris, France	EU/1/13/896	19.5.2015.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
13.5.2015.	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	19.5.2015.
13.5.2015.	Leflunomide ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/10/654	19.5.2015.
13.5.2015.	Luminity	Lantheus MI UK Limited Festival House, 39 Oxford Street, Newbury, Berkshire RG14 1JG, United Kingdom	EU/1/06/361	19.5.2015.
13.5.2015.	Memantine Merz	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/12/799	19.5.2015.
13.5.2015.	Ovitrelle	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/165	19.5.2015.
13.5.2015.	Trizivir	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/00/156	19.5.2015.
13.5.2015.	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	19.5.2015.
13.5.2015.	Vyndaqel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/11/717	19.5.2015.
27.5.2015.	Aflunov	Novartis Vaccines Influenza S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/658	29.5.2015.
27.5.2015.	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/283	29.5.2015.
27.5.2015.	Brinavess	Cardiome UK Limited Lakeside House, 1 Furzeground Way, Stockley Park, Uxbridge, Middlesex, UB11 1BD, United Kingdom	EU/1/10/645	29.5.2015.
27.5.2015.	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, D-27472 Cuxhaven, Deutschland	EU/1/09/555	29.5.2015.
27.5.2015.	Cometriq	TMC Pharma Services Ltd Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, Hampshire RG27 8AS, United Kingdom	EU/1/13/890	29.5.2015.
27.5.2015.	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/296	29.5.2015.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
27.5.2015.	Erivedge	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/848	29.5.2015.
27.5.2015.	Esmya	Gedeon Richter Plc. Gyömrői út 19-21., H-1103 Budapest, Magyarország	EU/1/12/750	29.5.2015.
27.5.2015.	Foclivia	Novartis Vaccines Influenza S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/09/577	29.5.2015.
27.5.2015.	Gardasil	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	29.5.2015.
27.5.2015.	Imnovid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/13/850	29.5.2015.
27.5.2015.	INCRELEX	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/07/402	29.5.2015.
27.5.2015.	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	29.5.2015.
27.5.2015.	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278	29.5.2015.
27.5.2015.	Levetiracetam Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/11/712	29.5.2015.
27.5.2015.	Myclausen	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, D-14167 Berlin, Deutschland	EU/1/10/647	29.5.2015.
27.5.2015.	Nexium Control	Pfizer Consumer Healthcare Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/13/860	29.5.2015.
27.5.2015.	Nivestim	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/631	29.5.2015.
27.5.2015.	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/453	29.5.2015.
27.5.2015.	Raloxifene Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/627	29.6.2015.
27.5.2015.	Relistor	TMC Pharma Services Ltd Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, Hampshire RG27 8AS, United Kingdom	EU/1/08/463	29.5.2015.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
27.5.2015.	Resolor	Shire Pharmaceuticals Ireland Limited 5 River Walk, Citywest Business Campus, Dublin 24, Ireland	EU/1/09/581	29.5.2015.
27.5.2015.	Selincro	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/12/815	29.5.2015.
27.5.2015.	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358	29.5.2015.
27.5.2015.	Sonata	Meda AB Pipers väg 2A, S-170 09 Solna, Sverige	EU/1/99/102	29.5.2015.
27.5.2015.	Sovaldi	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/894	29.5.2015.
27.5.2015.	Targretin	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire AL10 9SN, United Kingdom	EU/1/01/178	29.5.2015.
27.5.2015.	Temodal	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/98/096	29.5.2015.
27.5.2015.	Temozolomide Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/10/615	29.5.2015.
27.5.2015.	Thalidomide Celgene	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/08/443	29.5.2015.
27.5.2015.	Tolucombi	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/821	29.5.2015.
27.5.2015.	Volibris	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/08/451	29.5.2015.
27.5.2015.	Xeristar	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/297	29.5.2015.
27.5.2015.	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/13/846	29.5.2015.
27.5.2015.	Yentreve	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/280	29.5.2015.
27.5.2015.	Yondelis	Pharma Mar S.A. Avda de los Reyes 1, Polígono Industrial La Mina, E-28770 Colmenar Viejo, Madrid, España	EU/1/07/417	29.5.2015.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
28.5.2015.	Aclasta	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/05/308	1.6.2015.
28.5.2015.	alli	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/401	1.6.2015.
28.5.2015.	Dificlir	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/11/733	1.6.2015.
28.5.2015.	Invega	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/07/395	1.6.2015.
28.5.2015.	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383	1.6.2015.
28.5.2015.	Lonquex	UAB "Sicor Biotech" Molėtų pl. 5, LT-08409 Vilnius, Lietuva	EU/1/13/856	1.6.2015.
28.5.2015.	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	1.6.2015.
28.5.2015.	Topotecan Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633	1.6.2015.
28.5.2015.	Tygacil	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/06/336	1.6.2015.

— **Tirdzniecības atļaujas izņemšana no aprites** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants)

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
5.5.2015.	Clopidogrel DURA	Mylan dura GmbH Wittichstraße 6, D-64295 Darmstadt, Deutschland	EU/1/09/560	7.5.2015.
6.5.2015.	Provenge	Dendreon UK Limited 41 Chalton Street, London NW1 1JD, United Kingdom	EU/1/13/867	8.5.2015.

— **Tirdzniecības atļaujas grozīšana** (38. pants Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004): **Pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
5.5.2015.	MS-H Vaccine	Pharmsure International Ltd Unit 28, Moorlands Trading Estate, Moor Lane, Metheringham Lincolnshire, LN4 3HX, United Kingdom	EU/2/11/126	7.5.2015.
5.5.2015.	Purevax RCP	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/04/052	7.5.2015.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
13.5.2015.	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/98/006	19.5.2015.
13.5.2015.	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	19.5.2015.
27.5.2015.	Meloxivet	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/07/077	29.5.2015.
27.5.2015.	Purevax FeLV	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/00/019	29.5.2015.
27.5.2015.	Purevax RCPCh	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/04/050	29.5.2015.
27.5.2015.	Suprelorin	VIRBAC S.A. 1ère Avenue – 2065 m – L.I.D., F-06516 Carros CEDEX, France	EU/2/07/072	29.5.2015.

Ikvienam, kurš vēlas apskatīt publisko novērtējuma ziņojumu par attiecīgajām zālēm un ar tām saistītos lēmumus, jāsazinās ar:

The European Medicines Agency
30, Churchill Place, Canary Wharf
UK – LONDON E14 5EU

ISSN 1977-0952 (elektroniskais izdevums)
ISSN 1725-5201 (papīra izdevums)



Eiropas Savienības Publikāciju birojs
2985 Luksemburga
LUKSEMBURGA

LV