IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2017. gada 1. decembra līdz 2017. gada 31. decembrim

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

(2018/C 030/01)

([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
8.12.2017.	Tacforius	Tacrolimusum	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/17/1244	Ilgstošās darbības cietās kapsulas	L04AD02	12.12.2017.
18.12.2017.	Alecensa	alektinibs	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	Cietās kapsulas	L01XE36	20.12.2017.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
8.12.2017.	Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech	XBiotech Germany GmbH Lyoner Straße 14, 60528 Frankfurt am Main, Deutschland	—	12.12.2017.
18.12.2017.	Masipro	AB Science 3 avenue George V, 75008 Paris, France	—	20.12.2017.

— **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
1.12.2017.	Alecensa	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	5.12.2017.
1.12.2017.	Hetlioz	Vanda Pharmaceuticals Limited 25 Old Broad Street, level 21a, London EC2N 1HQ, United Kingdom	EU/1/15/1008	5.12.2017.
1.12.2017.	Jakavi	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/773	5.12.2017.
1.12.2017.	OCALIVA	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	EU/1/16/1139	5.12.2017.
1.12.2017.	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498	5.12.2017.
8.12.2017.	Ceplene	Noventia Pharma Srl Via Carlo Pisacane 31, 47121 Forli, Italia	EU/1/08/477	12.12.2017.
8.12.2017.	Dexdor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/718	12.12.2017.
8.12.2017.	Esbriet	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/11/667	13.12.2017.
8.12.2017.	Esmya	Gedeon Richter Plc. Gyömrői út 19-21., 1103 Budapest, Magyarország	EU/1/12/750	12.12.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
8.12.2017.	Genvoya	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/15/1061	12.12.2017.
8.12.2017.	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/677	13.12.2017.
8.12.2017.	Humira	AbbVie Ltd Abbvie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4UB, United Kingdom	EU/1/03/256	12.12.2017.
8.12.2017.	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383	13.12.2017.
8.12.2017.	JETREA	ThromboGenics NV Gaston Geenslaan 1, 3001 Leuven, België	EU/1/13/819	12.12.2017.
8.12.2017.	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	13.12.2017.
8.12.2017.	Leganto	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	EU/1/11/695	12.12.2017.
8.12.2017.	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	13.12.2017.
8.12.2017.	Moventig	Kyowa Kirin Limited Galabank Business Park, Galashiels, TD1 1QH, United Kingdom	EU/1/14/962	12.12.2017.
8.12.2017.	Mysimba	Orexigen Therapeutics Ireland Limited 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland	EU/1/14/988	12.12.2017.
8.12.2017.	Oncaspar	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/15/1070	14.12.2017.
8.12.2017.	Perjeta	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/813	13.12.2017.
8.12.2017.	Selincro	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/12/815	12.12.2017.
8.12.2017.	Taltz	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1085	12.12.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
8.12.2017.	Tesavel	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435	13.12.2017.
8.12.2017.	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1126	12.12.2017.
8.12.2017.	Xiapex	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/11/671	12.12.2017.
8.12.2017.	Zevalin	Spectrum Pharmaceuticals B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	EU/1/03/264	12.12.2017.
11.12.2017.	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1025	13.12.2017.
11.12.2017.	Holoclar	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/987	13.12.2017.
11.12.2017.	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/331	13.12.2017.
11.12.2017.	Odefsey	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/16/1112	13.12.2017.
11.12.2017.	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	15.12.2017.
11.12.2017.	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267	13.12.2017.
11.12.2017.	Strensiq	Alexion Europe SAS 1-15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	EU/1/15/1015	13.12.2017.
11.12.2017.	Tarceva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/05/311	13.12.2017.
11.12.2017.	Zyclara	Meda AB Pipers väg 2A, 170 73 Solna, Sverige	EU/1/12/783	13.12.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
15.12.2017.	Actelsar HCT	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/13/817	19.12.2017.
15.12.2017.	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	19.12.2017.
15.12.2017.	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	19.12.2017.
15.12.2017.	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	19.12.2017.
15.12.2017.	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	19.12.2017.
15.12.2017.	M-M-RVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/337	19.12.2017.
15.12.2017.	Procysbi	Chiesi Orphan B.V. Graadt van Roggenweg 340, 3531 AH Utrecht, Nederland	EU/1/13/861	19.12.2017.
15.12.2017.	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	19.12.2017.
15.12.2017.	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	19.12.2017.
15.12.2017.	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111	19.12.2017.
15.12.2017.	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110	19.12.2017.
15.12.2017.	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	19.12.2017.
18.12.2017.	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/14/939	20.12.2017.
18.12.2017.	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/126	20.12.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
18.12.2017.	HBVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/01/183	20.12.2017.
18.12.2017.	NovoMix	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/00/142	20.12.2017.
18.12.2017.	ProQuad	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/05/323	20.12.2017.
18.12.2017.	Xelevia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382	20.12.2017.
20.12.2017.	Azilect	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/04/304	22.12.2017.
20.12.2017.	Duloxetine Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/972	22.12.2017.
20.12.2017.	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	22.12.2017.
20.12.2017.	Efient	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/08/503	22.12.2017.
20.12.2017.	Fabrazyme	Genzyme Europe B.V. Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/01/188	22.12.2017.
20.12.2017.	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	22.12.2017.
20.12.2017.	Incresync	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/13/842	20.12.2017.
20.12.2017.	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/06/368	2.1.2018.
20.12.2017.	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/11/702	22.12.2017.
20.12.2017.	Levetiracetam SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/741	22.12.2017.
20.12.2017.	Qtern	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1108	22.12.2017.
20.12.2017.	Ranexa	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/08/462	22.12.2017.
20.12.2017.	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/13/892	22.12.2017.
20.12.2017.	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	22.12.2017.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 38. 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
1.12.2017.	Rabitec	Trakumsērgas vakcīna (dzīva, iekšķīgi lietojama) lapsām un jenotsuņiem	IDT Biologika GmbH Am Pharmapark, 06861 Dessau-Rosslau, Deutschland	EU/2/17/219	Suspensija iekšķīgai lietošanai	QI07BD	5.12.2017.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
6.12.2017.	Kexxtone	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/12/145	8.12.2017.
6.12.2017.	Spironolactone Ceva	Ceva Santé Animale 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/07/074	8.12.2017.
18.12.2017.	Sedadex	Le Vet Beheer B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/16/198	20.12.2017.
20.12.2017.	Easotic	VIRBAC S.A. 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	EU/2/08/085	22.12.2017.
20.12.2017.	Leucogen	Virbac 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	EU/2/09/096	22.12.2017.

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

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
UNITED KINGDOM