IV.

(Obavijesti)

OBAVIJESTI INSTITUCIJA, TIJELA, UREDA I AGENCIJA EUROPSKE UNIJE

EUROPSKA KOMISIJA

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. prosinca 2017. do 31. prosinca 2017.

(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ([1]))

(2018/C 030/01)

([1]) SL L 136, 30.4.2004., str. 1.

— **Izdavanje odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (medunarodni nezašticeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
8.12.2017.	Tacforius	takrolimus	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/17/1244	Tvrda kapsula s produljenim oslobađanjem	L04AD02	12.12.2017.
18.12.2017.	Alecensa	alektinib	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	Kapsula, tvrda	L01XE36	20.12.2017.

— **Izdavanje odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Odbijeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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 Pariz, France	—	20.12.2017.

— **Izmjena odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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 2 A, 170 73 Solna, Sverige	EU/1/12/783	13.12.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.	Duloksetin 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.

— **Izdavanje odobrenja za stavljanje u promet** (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (medunarodni nezašticeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
1.12.2017.	Rabitec	Cjepivo protiv bjesnoće (živo, oralno) za lisice i kunopse	IDT Biologika GmbH Am Pharmapark, 06861 Dessau-Rosslau, Deutschland	EU/2/17/219	Peroralna suspenzija	QI07BD	5.12.2017.

— **Izmjena odobrenja za stavljanje u promet** (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
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.

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

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