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 2015. do 31. prosinca 2015.

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

(2016/C 035/01)

([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
2.12.2015.	Ciambra	pemetrekseda	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/15/1055	Prašak za koncentrat za otopinu za infuziju	L01BA04	4.12.2015.
2.12.2015.	Nucala	mepolizumab	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	EU/1/15/1043	Prašak za otopinu za injekciju	Pending	7.12.2015.
16.12.2015.	Imlygic	Talimogene laherparepvec	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1064	Otopina za injekciju	Pending	18.12.2015.

— **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
21.12.2015.	Heparesc	Cytonet GmbH & Co. KG Albert-Ludwig-Grimm Straße 20, D-69469 Weinheim, Deutschland	—	23.12.2015.

— **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
2.12.2015.	Tadalafil Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/14/961	4.12.2015.
2.12.2015.	Twinrix Adult	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/96/020	4.12.2015.
2.12.2015.	Twinrix Paediatric	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/97/029	4.12.2015.
2.12.2015.	Zyclara	Meda AB Pipers väg 2A, SE-170 73 Solna, Sverige	EU/1/12/783	4.12.2015.
9.12.2015.	Abasaglar	Eli Lilly Regional Operations GmbH. Kölblgasse 8-10, 1030 Wien, Österreich	EU/1/14/944	11.12.2015.
9.12.2015.	Voriconazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/835	11.12.2015.
10.12.2015.	Accofil	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/14/946	14.12.2015.
10.12.2015.	Amyvid	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/12/805	14.12.2015.
10.12.2015.	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419	14.12.2015.
10.12.2015.	Efient	DAIICHI SANKYO EUROPE GmbH Zielstattstrasse 48, D-81379 München, Deutschland	EU/1/08/503	14.12.2015.
10.12.2015.	Gardasil	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	14.12.2015.
10.12.2015.	Holoclar	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/987	14.12.2015.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
10.12.2015.	Ifirmasta	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/480	14.12.2015.
10.12.2015.	Remsima	Celltrion Healthcare Hungary Kft. Árpád Fejedelem útja 26-28, H-1023 Budapest, Magyarország	EU/1/13/853	14.12.2015.
10.12.2015.	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358	14.12.2015.
10.12.2015.	Starlix	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/01/174	14.12.2015.
10.12.2015.	Synagis	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/99/117	14.12.2015.
10.12.2015.	Vipidia	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/13/844	14.12.2015.
10.12.2015.	Votubia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/710	14.12.2015.
10.12.2015.	Zoledronic acid Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Ísland	EU/1/12/759	14.12.2015.
14.12.2015.	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430	16.12.2015.
14.12.2015.	Envarsus	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/935	16.12.2015.
14.12.2015.	Incruse	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/922	16.12.2015.
14.12.2015.	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	16.12.2015.
14.12.2015.	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/452	16.12.2015.
14.12.2015.	Yervoy	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/698	16.12.2015.
16.12.2015.	Aldurazyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/253	18.12.2015.
16.12.2015.	Angiox	The Medicines Company UK Ltd 115L Milton Park, Abingdon, Oxfordshire OX14 4SA, United Kingdom	EU/1/04/289	18.12.2015.
16.12.2015.	AUBAGIO	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Pariz, France	EU/1/13/838	18.12.2015.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2015.	BYDUREON	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/696	18.12.2015.
16.12.2015.	Byetta	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/06/362	18.12.2015.
16.12.2015.	Caprelsa	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/749	18.12.2015.
16.12.2015.	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268	18.12.2015.
16.12.2015.	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	18.12.2015.
16.12.2015.	Emend	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262	18.12.2015.
16.12.2015.	Eucreas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/425	18.12.2015.
16.12.2015.	Fuzeon	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/252	18.12.2015.
16.12.2015.	Galvus	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/414	18.12.2015.
16.12.2015.	Icandra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/484	18.12.2015.
16.12.2015.	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/13/884	18.12.2015.
16.12.2015.	Jalra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/485	18.12.2015.
16.12.2015.	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, Northern Ireland BT51 3 RP, United Kindom	EU/1/03/270	21.12.2015.
16.12.2015.	Lyrica	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/04/279	18.12.2015.
16.12.2015.	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/767	18.12.2015.
16.12.2015.	ProQuad	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/05/323	18.12.2015.
16.12.2015.	Protopic	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/02/201	18.12.2015.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2015.	Stivarga	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/13/858	18.12.2015.
16.12.2015.	Tecfidera	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/13/837	22.12.2015.
16.12.2015.	Vfend	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/02/212	18.12.2015.
16.12.2015.	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/918	18.12.2015.
16.12.2015.	Xeplion	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/672	18.12.2015.
16.12.2015.	Xiliarx	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/486	18.12.2015.
16.12.2015.	Zomarist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/483	18.12.2015.
16.12.2015.	Zutectra	Biotest Pharma GmbH Landsteinerstrasse 5, D-63303 Dreieich, Deutschland	EU/1/09/600	18.12.2015.
18.12.2015.	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/958	22.12.2015.
18.12.2015.	Zostavax	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/341	22.12.2015.

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

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2015.	Osigraft	Olympus Biotech International Limited 40 Upper Mount Street, Dublin 2, Ireland	EU/1/01/179	21.12.2015.

— **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
9.12.2015.	Imrestor	pegbovigrastim	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/15/193	Otopina za injekciju	QL03AA90	11.12.2015.
9.12.2015.	Velactis	Kabergolin	Ceva Santé Animale 10 av. de La Ballastière, 33500 Libourne, France	EU/2/15/192	Otopina za injekciju	QG02CB03	11.12.2015.

— **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
2.12.2015.	Easotic	VIRBAC S.A. 1ère Avenue – 2065 m – L.I.D., F-06516 Carros Cedex, France	EU/2/08/085	4.12.2015.
2.12.2015.	Inflacam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/11/134	4.12.2015.
2.12.2015.	Purevax Rabies	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/10/117	4.12.2015.
18.12.2015.	Equip WNV	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/08/086	21.12.2015.
18.12.2015.	Novem	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/042	22.12.2015.
18.12.2015.	Purevax RC	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/04/051	22.12.2015.

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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