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 2014. do 31. prosinca 2014.

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

(2015/C 032/01)

([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 (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
5.12.2014.	Paliperidone Janssen	Paliperidon	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/971	Suspenzija s produljenim oslobađanjem za injekciju	N05AX13	9.12.2014.
8.12.2014.	Duloksetin Lilly	duloksetin	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/972	Želučanootporna tvrda kapsula	N06AX21	10.12.2014.
8.12.2014.	Moventig	naloksegol	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/962	Filmom obložena tableta	A06AH03	10.12.2014.
16.12.2014.	DUAVIVE	konjugirani estrogeni/bazedoksifen	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/14/960	Tableta s prilagođenim oslobađanjem	G03CX	18.12.2014.
16.12.2014.	Lynparza	Olaparib	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/959	Kapsula, tvrda	L01	18.12.2014.
19.12.2014.	Cyramza	ramucirumab	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/957	Koncentrat za otopinu za infuziju	L01XC	23.12.2014.
19.12.2014.	Rixubis	nonakog gama	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/14/970	Prašak i otapalo za otopinu za injekciju	B02BD04	23.12.2014.
22.12.2014.	Scenesse	afamelanotid	Clinuvel UK Limited c/o – Reed Smith, Broadgate Tower, Third Floor, 20 Primrose Street, London, EC2A 2RS, United Kingdom	EU/1/14/969	Implantant	D02BB02	29.12.2014.

— **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
1.12.2014.	Desloratadine Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/11/732	3.12.2014.
1.12.2014.	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/10/642	3.12.2014.
1.12.2014.	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/576	3.12.2014.
1.12.2014.	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	EU/1/07/398	3.12.2014.
4.12.2014.	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614	9.12.2014.
4.12.2014.	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444	8.12.2014.
4.12.2014.	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/445	8.12.2014.
5.12.2014.	Cystagon	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/97/039	9.12.2014.
5.12.2014.	Erbitux	Merck KGaA 64271 Darmstadt, Deutschland	EU/1/04/281	9.12.2014.
5.12.2014.	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	9.12.2014.
11.12.2014.	Bronchitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire SL1 7LW, United Kingdom	EU/1/12/760	15.12.2014.
11.12.2014.	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	15.12.2014.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
11.12.2014.	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	15.12.2014.
11.12.2014.	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/11/702	15.12.2014.
11.12.2014.	Removab	Neovii Biotech GmbH Am Haag 6-7, 82166 Graefelfing, Deutschland	EU/1/09/512	15.12.2014.
15.12.2014.	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134	18.12.2014.
15.12.2014.	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	17.12.2014.
15.12.2014.	Levetiracetam Actavis Group	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/738	18.12.2014.
15.12.2014.	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400	18.12.2014.
15.12.2014.	Naglazyme	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/05/324	17.12.2014.
15.12.2014.	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	18.12.2014.
15.12.2014.	Revestive	NPS Pharma Holdings Limited Grand Canal House, 1 Grand Canal Street Upper, Dublin 4, Ireland	EU/1/12/787	17.12.2014.
15.12.2014.	Somatropin Biopartners	BioPartners GmbH Kaiserpassage 11, D-72764 Reutlingen, Deutschland	EU/1/13/849	17.12.2014.
15.12.2014.	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/422	18.12.2014.
15.12.2014.	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	18.12.2014.
16.12.2014.	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538	18.12.2014.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2014.	Brintellix	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/13/891	18.12.2014.
16.12.2014.	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	17.12.2014.
16.12.2014.	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/00/170	18.12.2014.
16.12.2014.	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/11/687	18.12.2014.
16.12.2014.	HyQvia	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/13/840	18.12.2014.
16.12.2014.	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720	18.12.2014.
16.12.2014.	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	18.12.2014.
16.12.2014.	Levetiracetam Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/713	18.12.2014.
16.12.2014.	Methylthioninium chloride Proveblue	Provepharm S.A.S. 22 Rue Marc Donadille, 13013 Marseille, France	EU/1/11/682	18.12.2014.
16.12.2014.	NULOJIX	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/694	18.12.2014.
16.12.2014.	Orphacol	Laboratoires CTRS 63 rue de l'Est, F-92100 Boulogne-Billancourt, France	EU/1/13/870	18.12.2014.
16.12.2014.	Paglitaz	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/721	18.12.2014.
16.12.2014.	Pioglitazone Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/757	18.12.2014.
16.12.2014.	Pioglitazone Teva Pharma	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/758	18.12.2014.
16.12.2014.	Remsima	Celltrion Healthcare Hungary Kft. Árpád Fejedelem útja 26-28, H-1023 Budapest, Magyarország	EU/1/13/853	18.12.2014.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2014.	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	19.12.2014.
16.12.2014.	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	17.12.2014.
16.12.2014.	Stivarga	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/13/858	18.12.2014.
16.12.2014.	Ultibro Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/862	18.12.2014.
16.12.2014.	Ulunar Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/14/917	19.12.2014.
16.12.2014.	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	18.12.2014.
16.12.2014.	Xoterna Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/863	18.12.2014.
16.12.2014.	Zelboraf	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/12/751	19.12.2014.
19.12.2014.	CellCept	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/005	23.12.2014.
19.12.2014.	InductOs	Medtronic BioPharma B.V. Earl Bakkenstraat 10, NL-6422 PJ Heerlen, Nederland	EU/1/02/226	23.12.2014.
19.12.2014.	Puregon	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/008	23.12.2014.
19.12.2014.	Rilutek	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony CEDEX, France	EU/1/96/010	23.12.2014.
19.12.2014.	Stayveer	Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland	EU/1/13/832	5.1.2015.
19.12.2014.	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/610	24.12.2014.
19.12.2014.	Travatan	Alcon Laboratories (UK) Ltd Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom	EU/1/01/199	23.12.2014.
19.12.2014.	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	23.12.2014.
19.12.2014.	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	24.12.2014.
19.12.2014.	Zoledronic acid Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/772	24.12.2014.

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

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
22.12.2014.	Bovela	Modificirani živi BVDV-1 necitopatogeni roditeljski soj KE-9, Modificirani živi BVDV-2 necitopatogeni roditeljski soj NY-93	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/176	Liofilizat i otapalo, suspenzija za injekciju	QI02AD02	29.12.2014.

— **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
4.12.2014.	Gripovac 3	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/09/102	8.12.2014.
4.12.2014.	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/00/026	8.12.2014.
4.12.2014.	Respiporc Flu3	IDT Biologika GmbH Am Pharmapark, D-06861 Dessau-Rosslau, Deutschland	EU/2/09/103	8.12.2014.
11.12.2014.	Comfortis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/10/115	15.12.2014.
11.12.2014.	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/13/155	15.12.2014.
16.12.2014.	Pexion	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/12/147	18.12.2014.

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

The European Medicines Agency
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