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. lipnja 2016. do 30. lipnja 2016.

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

(2016/C 277/01)

([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
21.6.2016.	Odefsey	emtricitabin/rilpivirin/tenofoviralafenamid	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/16/1112	Filmom obložena tableta	J05AR19	23.6.2016.
24.6.2016.	Ongentys	opikapon	Bial – Portela & C[a], SA À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/15/1066	Kapsula, tvrda	Pending	28.6.2016.
24.6.2016.	Zavicefta	ceftazidim/avibaktam	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1109	Prašak za koncentrat za otopinu za infuziju	J01DD52	28.6.2016.
29.6.2016.	Enzepi	gušterača, prašak	APTALIS PHARMA SAS 5/6 Place de l'Iris – La Défense 5 92400 Courbevoie France	EU/1/16/1113	Tvrda želučanootporna kapsula.	A09AA02	1.7.2016.

— **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
24.6.2016.	Dropcys	Lucane Pharma 172 rue de Charonne, 75011 Pariz, France		28.6.2016.

— **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
1.6.2016.	Cotellic	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/15/1048	3.6.2016.
1.6.2016.	HyQvia	Baxalta Innovations GmbH Industriestrasse 67, A-1221 Wien, Österreich	EU/1/13/840	6.6.2016.
1.6.2016.	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	3.6.2016.
1.6.2016.	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/785	3.6.2016.
2.6.2016.	Adrovance	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/364	6.6.2016.
2.6.2016.	Altargo	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/390	6.6.2016.
2.6.2016.	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300	6.6.2016.
2.6.2016.	Capecitabine Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/762	6.6.2016.
2.6.2016.	Clopidogrel BGR	Laboratoires BIOGARAN 15 boulevard Charles de Gaulle, 92707 Colombes Cedex, France	EU/1/09/558	6.6.2016.
2.6.2016.	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	7.6.2016.
2.6.2016.	Clopidogrel ratiopharm GmbH	Archie Samuel s.r.o. Slunná 16, CZ-61700 Brno, Česká republika	EU/1/09/541	6.6.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
2.6.2016.	Imatinib Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Ísland	EU/1/13/825	6.6.2016.
2.6.2016.	Kineret	Swedish Orphan Biovitrum AB (publ) SE-112 76 Stockholm, Sverige	EU/1/02/203	7.6.2016.
2.6.2016.	Kiovig	Baxter AG Industriestrasse 67, A-1221 Wien, Österreich	EU/1/05/329	6.6.2016.
2.6.2016.	Lonquex	UAB „Sicor Biotech” Molėtų pl. 5, LT-08409 Vilnius, Lietuva	EU/1/13/856	6.6.2016.
2.6.2016.	Neuraceq	Piramal Imaging Limited Langstone Technology Park, Langstone Road, Havant, Hampshire, PO9 1SA, United Kingdom	EU/1/13/906	6.6.2016.
2.6.2016.	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/422	6.6.2016.
2.6.2016.	Temozolomide Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/10/615	6.6.2016.
2.6.2016.	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/08/470	6.6.2016.
9.6.2016.	Cubicin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/328	13.6.2016.
9.6.2016.	Telmisartan Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/719	13.6.2016.
9.6.2016.	VPRIV	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/10/646	13.6.2016.
9.6.2016.	Zyllt	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553	13.6.2016.
13.6.2016.	Gazyvaro	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/14/937	15.6.2016.
16.6.2016.	Advagraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/07/387	20.6.2016.
16.6.2016.	Avonex	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/97/033	20.6.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.6.2016.	Protopic	Leo Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/02/201	20.6.2016.
16.6.2016.	Tesavel	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435	20.6.2016.
16.6.2016.	Xelevia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382	20.6.2016.
21.6.2016.	Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A Viale Shakespeare 47, 00144 Roma, Italia	EU/1/11/716	23.6.2016.
21.6.2016.	Irbesartan Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Pariz, France	EU/1/06/376	23.6.2016.
21.6.2016.	Karvea	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Pariz, France	EU/1/97/049	23.6.2016.
21.6.2016.	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	23.6.2016.
21.6.2016.	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/09/523	23.6.2016.
21.6.2016.	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267	23.6.2016.
21.6.2016.	Zometa	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/01/176	23.6.2016.
24.6.2016.	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	28.6.2016.
24.6.2016.	Advate	Baxter AG Industriestrasse 67, A-1221 Wien, Österreich	EU/1/03/271	28.6.2016.
24.6.2016.	Aprovel	Sanofi Clir SNC 54 rue La Boétie, F-75008 Pariz, France	EU/1/97/046	28.6.2016.
24.6.2016.	Cubicin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/328	28.6.2016.
24.6.2016.	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/14/939	28.6.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
24.6.2016.	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/03/261	28.6.2016.
24.6.2016.	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	28.6.2016.
24.6.2016.	Humira	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/03/256	28.6.2016.
24.6.2016.	Imnovid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/13/850	28.6.2016.
24.6.2016.	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383	28.6.2016.
24.6.2016.	Rasilez	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/405	28.6.2016.
24.6.2016.	Rasilez HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/491	28.6.2016.
24.6.2016.	Relvar Ellipta	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/13/886	28.6.2016.
24.6.2016.	Revinty Ellipta	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/929	28.6.2016.
24.6.2016.	Simponi	Janssen Biologics B.V. Einsteinweg 101, NL-2333 CB Leiden, Nederland	EU/1/09/546	28.6.2016.
24.6.2016.	Tolura	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/10/632	28.6.2016.
24.6.2016.	Tysabri	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/06/346	28.6.2016.
24.6.2016.	Zoledronic acid Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/12/800	28.6.2016.
29.6.2016.	Champix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/06/360	1.7.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
29.6.2016.	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720	1.7.2016.
29.6.2016.	Kivexa	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/298	1.7.2016.
29.6.2016.	Kyprolis	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1060	1.7.2016.
29.6.2016.	Matever	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/11/711	1.7.2016.
29.6.2016.	Memantine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/13/827	8.7.2016.
29.6.2016.	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/08/448	1.7.2016.
29.6.2016.	PegIntron	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/131	1.7.2016.
29.6.2016.	Revestive	NPS Pharma Holdings Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/12/787	1.7.2016.
29.6.2016.	Tyverb	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/440	1.7.2016.
29.6.2016.	Vidaza	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom	EU/1/08/488	1.7.2016.
29.6.2016.	ViraferonPeg	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/132	4.7.2016.
29.6.2016.	Yondelis	Pharma Mar S.A. Avda de los Reyes 1, Polígono Industrial La Mina, E-28770 Colmenar Viejo, Madrid, España	EU/1/07/417	1.7.2016.
29.6.2016.	Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6, D-22880 Wedel, Deutschland	EU/1/12/779	1.7.2016.
30.6.2016.	Ceplene	Meda AB Box 906, SE-170 09 Solna, Sverige	EU/1/08/477	5.7.2016.
30.6.2016.	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	4.7.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
30.6.2016.	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	4.7.2016.
30.6.2016.	Eylea	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/12/797	4.7.2016.
30.6.2016.	Filgrastim Hexal	Hexal AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/08/496	4.7.2016.
30.6.2016.	Hycamtin	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/96/027	4.7.2016.
30.6.2016.	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	4.7.2016.
30.6.2016.	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/924	4.7.2016.
30.6.2016.	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	4.7.2016.
30.6.2016.	Toujeo	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	4.7.2016.
30.6.2016.	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	4.7.2016.
30.6.2016.	Yentreve	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/280	4.7.2016.
30.6.2016.	Zarzio	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/08/495	4.7.2016.

— **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
1.6.2016.	Klopidogrel/acetilsalicilatna kiselina Teva	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/942	3.6.2016.
21.6.2016.	Capecitabine SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland	EU/1/13/831	23.6.2016.
30.6.2016.	Krystexxa	Crealta Pharmaceuticals Ireland Limited Commercial House, Millbank Business Park, Lower Lucan Road, Lucan, Co.Dublin, Ireland	EU/1/12/810	4.7.2016.
30.6.2016.	Opgenra	Olympus Biotech International Limited 40 Upper Mount Street, Dublin 2, Ireland	EU/1/08/489	4.7.2016.

— **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
21.6.2016.	Sevocalm	sevofluran	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/16/196	Para inhalata, tekućina	Pending	24.6.2016.

— **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
3.6.2016.	Nobivac L4	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/12/143	7.6.2016.
21.6.2016.	Emdocam	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/11/128	23.6.2016.
21.6.2016.	Metacam	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/97/004	23.6.2016.
22.6.2016.	Nobilis Influenza H5N2	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/06/061	24.6.2016.
24.6.2016.	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090	29.6.2016.

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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