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 2016. do 31. prosinca 2016.

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

(2017/C 028/01)

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([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
5.12.2016.	Venclyxto	venetoklaks	AbbVie Ltd Vanwall Road, Maidenhead, SL6 4UB, United Kingdom	EU/1/16/1138	Filmom obložena tableta	L01X	7.12.2016.
8.12.2016.	Emtricitabine/Tenofovir disoproxil Krka	emtricitabin/tenofovirdizoproksil	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/16/1151	Filmom obložena tableta	J05AR03	12.12.2016.
8.12.2016.	SomaKit TOC	edotreotid	Advanced Accelerator Applications 20 rue Diesel, F-1630 Saint-Genis-Pouilly, France	EU/1/16/1141	Prašak za otopinu za injekciju	V09IX09	12.12.2016.
8.12.2016.	Tenofovir disoproxil Mylan	Tenofovirdizoproksil	MYLAN S.A.S 117 Allée des Parcs, 69800 Saint-Priest, France	EU/1/16/1129	Filmom obložena tableta	J05AF07	12.12.2016.
12.12.2016.	OCALIVA	obetikolatne kiseline	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	EU/1/16/1139	Filmom obložena tableta	A05AA04	15.12.2016.
12.12.2016.	Rekovelle	folitropina delta	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 Copenhagen S, Danmark	EU/1/16/1150		G03GA10	14.12.2016.
16.12.2016.	Emtricitabine/Tenofovir disoproxil Mylan	emtricitabin/tenofovirdizoproksil	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/16/1133	Filmom obložena tableta	J05AR03	20.12.2016.

— **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
2.12.2016.	Aclasta	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/05/308	6.12.2016.
5.12.2016.	Pioglitazone Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/11/722	7.12.2016.
5.12.2016.	Spedra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/13/841	7.12.2016.
5.12.2016.	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1126	7.12.2016.
8.12.2016.	Actraphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/229	12.12.2016.
8.12.2016.	Actrapid	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/230	12.12.2016.
8.12.2016.	Adenuric	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/08/447	12.12.2016.
8.12.2016.	Bosulif	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/13/818	12.12.2016.
8.12.2016.	CONTROLOC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/515	12.12.2016.
8.12.2016.	Cystadane	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/06/379	12.12.2016.
8.12.2016.	DuoPlavin	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/10/619	12.12.2016.
8.12.2016.	Eperzan	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	EU/1/13/908	14.12.2016.
8.12.2016.	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/677	12.12.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
8.12.2016.	Holoclar	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/987	12.12.2016.
8.12.2016.	Icandra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/484	12.12.2016.
8.12.2016.	Lamivudine/Zidovudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/663	12.12.2016.
8.12.2016.	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292	5.12.2016.
8.12.2016.	Otezla	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/14/981	12.12.2016.
8.12.2016.	PANTOZOL Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/517	12.12.2016.
8.12.2016.	SOMAC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/516	12.12.2016.
8.12.2016.	Voriconazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/835	12.12.2016.
8.12.2016.	Zebinix	Bial – Portela & C[a], SA À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/09/514	12.12.2016.
8.12.2016.	Zoledronic acid Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/12/759	12.12.2016.
9.12.2016.	Ecansya	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	12.12.2016.
12.12.2016.	Accofil	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/14/946	14.12.2016.
12.12.2016.	Aldara	Meda AB Pipers väg 2A, SE-170 73 Solna, Sverige	EU/1/98/080	14.12.2016.
12.12.2016.	Aripiprazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/15/1045	14.12.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.12.2016.	Colobreathe	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/747	14.12.2016.
12.12.2016.	Cometriq	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/13/890	14.12.2016.
12.12.2016.	Competact	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/06/354	14.12.2016.
12.12.2016.	Crixivan	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/024	14.12.2016.
12.12.2016.	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	EU/1/12/770	15.12.2016.
12.12.2016.	Ebymect	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/15/1051	14.12.2016.
12.12.2016.	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	14.12.2016.
12.12.2016.	Eucreas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/425	14.12.2016.
12.12.2016.	Flebogamma DIF	Instituto Grifols, S.A. Can Guasch 2, Parets del Vallès, E-08150 Barcelona, España	EU/1/07/404	14.12.2016.
12.12.2016.	Glubrava	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/07/421	14.12.2016.
12.12.2016.	Humira	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/03/256	14.12.2016.
12.12.2016.	Inflectra	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/13/854	14.12.2016.
12.12.2016.	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	14.12.2016.
12.12.2016.	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	14.12.2016.
12.12.2016.	Komboglyze	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/731	14.12.2016.
12.12.2016.	Kyprolis	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1060	14.12.2016.
12.12.2016.	Lynparza	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/959	14.12.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.12.2016.	Mysimba	Orexigen Therapeutics Ireland Limited 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland	EU/1/14/988	14.12.2016.
12.12.2016.	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/767	14.12.2016.
12.12.2016.	NovoMix	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/00/142	14.12.2016.
12.12.2016.	Optaflu	Seqirus GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland	EU/1/07/394	14.12.2016.
12.12.2016.	Orbactiv	The Medicines Company UK Ltd 115L Milton Park, Abingdon, Oxfordshire OX14 4SA, United Kingdom	EU/1/15/989	14.12.2016.
12.12.2016.	Pregabalin Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/15/1027	14.12.2016.
12.12.2016.	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	14.12.2016.
12.12.2016.	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	14.12.2016.
12.12.2016.	TAGRISSO	AstraZeneca AB Gärtunavägen, SE-151 85 Södertälje, Sverige	EU/1/16/1086	14.12.2016.
12.12.2016.	Trulicity	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/956	14.12.2016.
12.12.2016.	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	14.12.2016.
12.12.2016.	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/08/470	14.12.2016.
12.12.2016.	Vipdomet	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/13/843	14.12.2016.
12.12.2016.	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/918	14.12.2016.
12.12.2016.	Xigduo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/900	14.12.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
12.12.2016.	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/13/846	14.12.2016.
12.12.2016.	Zomarist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/483	14.12.2016.
13.12.2016.	GONAL-f	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/95/001	16.12.2016.
16.12.2016.	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430	21.12.2016.
16.12.2016.	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/11/749	20.12.2016.
16.12.2016.	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, Northern Ireland BT51 3 RP, United Kindom	EU/1/03/270	20.12.2016.
16.12.2016.	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278	20.12.2016.
16.12.2016.	Mixtard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/231	20.12.2016.
16.12.2016.	Pemetrexed Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1034	20.12.2016.
16.12.2016.	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	20.12.2016.
16.12.2016.	RotaTeq	Sanofi Pasteur MSD SAS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/348	20.12.2016.
16.12.2016.	Sebivo	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/388	20.12.2016.
19.12.2016.	Entyvio	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/14/923	21.12.2016.
19.12.2016.	Pemetrexed Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/15/1037	21.12.2016.
19.12.2016.	Tractocile	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 Copenhagen S, Danmark	EU/1/99/124	21.12.2016.
19.12.2016.	Visudyne	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/00/140	21.12.2016.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.12.2016.	Duloxetine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/15/1010	5.1.2017.
23.12.2016.	Fareston	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/96/004	4.1.2017.
23.12.2016.	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026	4.1.2017.
23.12.2016.	Mepact	Takeda France SAS Immeuble Pacific, 11-13 cours Valmy, 92800 Puteaux, France	EU/1/08/502	4.1.2017.
23.12.2016.	Orkambi	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/15/1059	4.1.2017.
23.12.2016.	Raplixa	Mallinckrodt Pharmaceuticals Ireland Limited College Business & Technology Park Cruiserath, Blanchardstown, Dublin 15, Ireland	EU/1/14/985	4.1.2017.
23.12.2016.	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/13/901	4.1.2017.

— **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
16.12.2016.	Budesonide/Formoterol Teva	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/948	20.12.2016.
16.12.2016.	Budesonide/Formoterol Teva Pharma B.V.	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/950	20.12.2016.

— **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
13.12.2016.	Cepedex	deksmedetomidin	CP Pharma Handelsgesellschaft mbH Ostlandring 13, D-31303 Burgdorf, Deutschland	EU/2/16/200	Otopina za injekciju	QN05CM18	15.12.2016.
13.12.2016.	Halagon	halofuginon	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/16/201	Peroralna otopina	QP51AX08	15.12.2016.

— **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
13.12.2016.	Parvoduk	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/14/162	15.12.2016.
13.12.2016.	Zulvac 1+8 Bovis	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/139	15.12.2016.
14.12.2016.	Activyl Tick Plus	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/11/137	16.12.2016.
14.12.2016.	Porcilis PCV M Hyo	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/14/175	16.12.2016.
14.12.2016.	Versican Plus DHPPi	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/169	16.12.2016.
14.12.2016.	Versican Plus DHPPi/L4	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/164	16.12.2016.
14.12.2016.	Versican Plus DHPPi/L4R	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/163	16.12.2016.

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

European Medicines Agency
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Canary Wharf
London E14 5EU
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