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. srpnja 2017. do 31. kolovoza 2017.

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

(2017/C 328/01)

([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
6.7.2017.	OXERVATE	cenegermin	Dompé farmaceutici S.p.A. Via Santa Lucia 6, 20122 Milano, Italia	EU/1/17/1197	Kapi za oko, otopina	Pending	10.7.2017.
10.7.2017.	Spherox	sferoidi ljudskih autolognih hondrocita vezanih na matriks	CO.DON AG Warthestraße 21, 14513 Teltow, Deutschland	EU/1/17/1181	Suspenzija implantata	M09AX02	12.7.2017.
13.7.2017.	Blitzima	rituksimab	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1205	Koncentrat za otopinu za infuziju	L01XC02	17.7.2017.
13.7.2017.	Reagila	kariprazina	Gedeon Richter Plc. Gyömrői út 19-21., H-1103 Budapest, Magyarország	EU/1/17/1209	Kapsula, tvrda	N05AX15	17.7.2017.
13.7.2017.	Ritemvia	rituksimab	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1207	Koncentrat za otopinu za infuziju	L01XC02	17.7.2017.
13.7.2017.	Tuxella	rituksimab	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1206	Koncentrat za otopinu za infuziju	L01XC02	17.7.2017.
17.7.2017.	Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva	efavirenz/emtricitabin/tenofovirdizoproksil	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/17/1210	Filmom obložena tableta	J05AR06	19.7.2017.
17.7.2017.	Kyntheum	brodalumab	Leo Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/16/1155	Otopina za injekciju	L04AC12	19.7.2017.

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
17.7.2017.	Trimbow	beklometazon/ formoterol/glikopironij bromid	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/17/1208	Stlačeni inhalat, otopina	R03AL09	19.7.2017.
19.7.2017.	Insulin lispro Sanofi	inzulin lispro	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/17/1203	Otopina za injekciju	A10AB04	21.7.2017.
19.7.2017.	Veltassa	patiromer	Vifor Fresenius Medical Care Renal Pharma France 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/17/1179	Prašak za oralnu suspenziju	V03AE09	21.7.2017.
26.7.2017.	Maviret	glekaprevir/pibrentasvir.	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/17/1213	Filmom obložena tableta	J05AX	28.7.2017.
26.7.2017.	Vosevi	sofosbuvir/velpatasvir/voksilaprevir	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/17/1223	Filmom obložena tableta	Pending	28.7.2017.
26.7.2017.	Zykadia	ceritinib	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/999	Kapsula, tvrda	L01XE28	28.7.2017.
22.8.2017.	Kisqali	ribociklib	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/17/1221	Filmom obložena tableta	L01XE42	24.8.2017.
22.8.2017.	MAVENCLAD	kladribin	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/17/1212	Tableta	L01BB04	24.8.2017.

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
24.8.2017.	Fotivda	tivozanib	EUSA Pharma (UK) Limited Breakspear Park, Breakspear Way, HP2 4TZ, Hemel Hempstead, United Kingdom	EU/1/17/1215	Kapsula, tvrda	L01XE34	29.8.2017.
24.8.2017.	Imraldi	adalimumab	Samsung Bioepis UK Limited 5th floor, Profile West, 950 Great West Road, Brentford, Middlesex TW8 9ES, United Kingdom	EU/1/17/1216	Otopina za injekciju	L04AB04	29.8.2017.
24.8.2017.	Nitisinone MendeliKABS	nitizinon	MendeliKABS Europe Limited Office 7, Gateway 1000, Whittle Way, Stevenage, Hertfordshire, SG1 2FP, United Kingdom	EU/1/17/1217	Kapsula, tvrda	A16AX04	29.8.2017.

— **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
6.7.2017.	Celsentri	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/07/418	10.7.2017.
6.7.2017.	Clopidogrel Krka d. d.	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	10.7.2017.
6.7.2017.	Imlygic	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1064	10.7.2017.
6.7.2017.	Kivexa	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/298	10.7.2017.
6.7.2017.	Nexavar	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/06/342	10.7.2017.
6.7.2017.	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386	10.7.2017.
10.7.2017.	Memantin Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/880	12.7.2017.
10.7.2017.	Myozyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/06/333	12.7.2017.
10.7.2017.	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	12.7.2017.
13.7.2017.	Edistride	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/15/1052	17.7.2017.
13.7.2017.	Enurev Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/789	17.7.2017.
13.7.2017.	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	17.7.2017.
13.7.2017.	Incruse	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/922	17.7.2017.
13.7.2017.	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436	17.7.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
13.7.2017.	Kuvan	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, Ireland	EU/1/08/481	17.7.2017.
13.7.2017.	Latuda	Sunovion Pharmaceuticals Europe Ltd First Floor, Southside, 97-105 Victoria Street, London SW1E 6QT, United Kingdom	EU/1/14/913	17.7.2017.
13.7.2017.	Lixiana	Daiichi Sankyo Europe GmbH Zielstattstrasse 48, D-81379 München, Deutschland	EU/1/15/993	17.7.2017.
13.7.2017.	Memantine Merz	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/12/799	17.7.2017.
13.7.2017.	Picato	LEO Laboratories Ltd. 285 Cashel Road, Crumlin, Dublin 12, Ireland	EU/1/12/796	17.7.2017.
13.7.2017.	Praxbind	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1056	17.7.2017.
13.7.2017.	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/424	17.7.2017.
13.7.2017.	Xaluprine	Nova Laboratories Limited Martin House, Gloucester Crescent, Wigston Leicester, LE18 4YL, United Kingdom	EU/1/11/727	17.7.2017.
13.7.2017.	Xultophy	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/14/947	17.7.2017.
13.7.2017.	Zalmoxis	MolMed S.p.A. Via Olgettina 58, I-20132 Milano, Italia	EU/1/16/1121	17.7.2017.
13.7.2017.	Zoledronic acid Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/834	17.7.2017.
14.7.2017.	Zinbryta	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/16/1107	18.7.2017.
17.7.2017.	Dinutuximab beta Apeiron	EUSA Pharma (UK) Limited Breakspear Park, Breakspear Way, HP2 4TZ, Hemel Hempstead, United Kingdom	EU/1/17/1191	19.7.2017.
17.7.2017.	Inhixa	Techdow Europe AB Kåbovägen 32, 75236 Uppsala, Sverige	EU/1/16/1132	20.7.2017.
17.7.2017.	Opsumit	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/13/893	19.7.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
17.7.2017.	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/09/599	19.7.2017.
17.7.2017.	Thorinane	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077XX Amsterdam, Nederland	EU/1/16/1131	19.7.2017.
17.7.2017.	Zinforo	Pfizer Ireland Pharmaceuticals Operations Services Group, Ringaskiddy, County Cork, Ireland	EU/1/12/785	19.7.2017.
19.7.2017.	Clopidogrel BGR	Laboratoires BIOGARAN 15 boulevard Charles de Gaulle, 92707 Colombes Cedex, France	EU/1/09/558	21.7.2017.
19.7.2017.	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	21.7.2017.
19.7.2017.	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, D-27472 Cuxhaven, Deutschland	EU/1/09/555	21.7.2017.
19.7.2017.	Cuprymina	SPARKLE S.r.l. Località Cavallino, 62010 Montecosaro (MC), Italia	EU/1/12/784	24.7.2017.
19.7.2017.	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	24.7.2017.
19.7.2017.	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	21.7.2017.
19.7.2017.	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/958	24.7.2017.
19.7.2017.	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	21.7.2017.
19.7.2017.	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	21.7.2017.
19.7.2017.	Qtern	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1108	24.7.2017.
19.7.2017.	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Strasse 8, D-79539 Lörrach, Deutschland	EU/1/15/1020	24.7.2017.
19.7.2017.	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	21.7.2017.
19.7.2017.	Seebri Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/788	21.7.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.7.2017.	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	21.7.2017.
19.7.2017.	Tracleer	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220	21.7.2017.
19.7.2017.	Zavesca	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/238	21.7.2017.
19.7.2017.	Zavicefta	Pfizer Ireland Pharmaceuticals Operations Services Group, Ringaskiddy, County Cork, Ireland	EU/1/16/1109	24.7.2017.
25.7.2017.	Faslodex	AstraZeneca UK Limited Charter Way, Macclesfield, Cheshire, SK10 2NA, United Kingdom	EU/1/03/269	27.7.2017.
25.7.2017.	Granupas	Lucane Pharma 172 rue de Charonne, 75011 Paris, France	EU/1/13/896	27.7.2017.
25.7.2017.	Olanzapine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/08/475	31.7.2017.
25.7.2017.	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389	27.7.2017.
25.7.2017.	Rivastigmine 1 A Pharma	1 A Pharma GmbH Keltenring 1 + 3, D-82041 Oberhaching, Deutschland	EU/1/09/585	28.7.2017.
25.7.2017.	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	27.7.2017.
25.7.2017.	Voncento	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/13/857	28.7.2017.
26.7.2017.	Aripiprazole Mylan Pharma	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/15/1005	28.7.2017.
26.7.2017.	Bridion	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/466	28.7.2017.
26.7.2017.	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	28.7.2017.
26.7.2017.	Oprymea	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/469	28.7.2017.
26.7.2017.	Tovanor Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/790	28.7.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
26.7.2017.	Velphoro	Vifor Fresenius Medical Care Renal Pharma France 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/14/943	28.7.2017.
26.7.2017.	Votubia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/710	28.7.2017.
26.7.2017.	Yellox	PharmaSwiss Česká republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 Česká republika	EU/1/11/692	28.7.2017.
2.8.2017.	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	4.8.2017.
2.8.2017.	Zyllt	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553	4.8.2017.
3.8.2017.	Abilify	Otsuka Pharmaceutical Europe Ltd. Gallions, Wexham Springs, Framewood Road, Wexham, SL3 6PJ, United Kingdom	EU/1/04/276	17.8.2017.
3.8.2017.	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285	7.8.2017.
7.8.2017.	Colobreathe	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/747	9.8.2017.
7.8.2017.	Nordimet	Nordic Group B.V. Siriusdreef 22, NL-2132 WT Hoofddorp, Nederland	EU/1/16/1124	9.8.2017.
7.8.2017.	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	9.8.2017.
14.8.2017.	Exjade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/356	17.8.2017.
14.8.2017.	Mekinist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/14/931	18.8.2017.
14.8.2017.	Soliris	Alexion Europe SAS 1-15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	EU/1/07/393	17.8.2017.
14.8.2017.	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	17.8.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
14.8.2017.	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	17.8.2017.
22.8.2017.	CoAprovel	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/086	24.8.2017.
22.8.2017.	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	EU/1/14/965	24.8.2017.
22.8.2017.	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	24.8.2017.
22.8.2017.	SonoVue	Bracco International B.V. Strawinskylaan 3051, NL-1077 ZX Amsterdam, Nederland	EU/1/01/177	24.8.2017.
22.8.2017.	Xarelto	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/08/472	24.8.2017.
24.8.2017.	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185	28.8.2017.
24.8.2017.	BYDUREON	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/696	28.8.2017.
24.8.2017.	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	28.8.2017.
24.8.2017.	EDURANT	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/736	28.8.2017.
24.8.2017.	Fluenz Tetra	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/887	28.8.2017.
24.8.2017.	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	28.8.2017.
24.8.2017.	Invega	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/07/395	28.8.2017.
24.8.2017.	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	29.8.2017.
24.8.2017.	Karvezide	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/085	28.8.2017.
24.8.2017.	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	29.8.2017.
24.8.2017.	Norvir	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/96/016	29.8.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
24.8.2017.	Orkambi	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/15/1059	29.8.2017.
24.8.2017.	Ruconest	Pharming Group N.V. Darwinweg 24, NL-2333 CR Leiden, Nederland	EU/1/10/641	28.8.2017.
24.8.2017.	Zoledronic acid Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/12/800	29.8.2017.
28.8.2017.	Constella	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/12/801	30.8.2017.
28.8.2017.	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416	30.8.2017.
28.8.2017.	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	30.8.2017.
28.8.2017.	Irbesartan HCT Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/06/377	30.8.2017.
28.8.2017.	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292	30.8.2017.
28.8.2017.	Rasilez HCT	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/08/491	30.8.2017.

— **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
19.7.2017.	Enzepi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1113	21.7.2017.
19.7.2017.	Repso	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/674	21.7.2017.

— **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
17.8.2017.	VEPURED	Cjepivo protiv bakterije *Escherichia coli* koja proizvodi verotoxin (inaktivirani recombinant)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/17/214	Suspenzija za injekciju	QI09AB02	21.8.2017.
18.8.2017.	Exzolt	fluralaner	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/17/212	Suspenzija za upotrebu u vodi za piće	QP53BE02	22.8.2017.
22.8.2017.	Innovax-ND-IBD	Newcastle bolest, zarazna bolest burze i cjepivo za Marekovu bolest (živo rekombinirano)	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/17/213	Suspenzija i otapalo za suspenziju za injekciju	QI01AD	24.8.2017.
24.8.2017.	Suvaxyn PRRS MLV	Cjepivo koje sadrži virus respiratornog i reproduktivnog sindroma svinja (živi)	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	Liofilizat i otapalo, suspenzija za injekciju	QI09AD03	28.8.2017.

— **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
10.7.2017.	Onsior	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/08/089	12.7.2017.
14.7.2017.	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/14/174	18.7.2017.
14.7.2017.	Zolvix	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/09/101	18.7.2017.
19.7.2017.	Aivlosin	ECO Animal Health Ltd 78 Coombe Road, New Malden, Surrey KT3 4QS United Kingdom	EU/2/04/044	21.7.2017.
28.7.2017.	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090	1.8.2017.
28.7.2017.	Vaxxitek HVT + IBD	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/02/032	1.8.2017.
3.8.2017.	BLUEVAC BTV8	CZ Veterinaria, S.A. La Relva s/n, 36400 Porriño, España	EU/2/11/122	7.8.2017.
10.8.2017.	Canigen L4	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/15/183	14.8.2017.

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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