IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2016. gada 1. decembra līdz 2016. gada 31. decembrim

(Publicēts saskaņā ar Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 ([1]) 13. vai 38. pantu)

(2017/C 028/01)

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([1]) OV L 136, 30.4.2004., 1. lpp.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	INN (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
5.12.2016.	Venclyxto	venetoklakss	AbbVie Ltd Vanwall Road, Maidenhead, SL6 4UB, United Kingdom	EU/1/16/1138	Apvalkotās tabletes	L01X	7.12.2016.
8.12.2016.	Emtricitabine/Tenofovir disoproxil Krka	emtricitabīns/tenofovīra disoproksils	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/16/1151	Apvalkotās tabletes	J05AR03	12.12.2016.
8.12.2016.	SomaKit TOC	edotreotide	Advanced Accelerator Applications 20 rue Diesel, F-1630 Saint-Genis-Pouilly, France	EU/1/16/1141	Pulveris injekciju šķīduma pagatavošanai	V09IX09	12.12.2016.
8.12.2016.	Tenofovir disoproxil Mylan	Tenofovīra disoproksila	MYLAN S.A.S 117 Allée des Parcs, 69800 Saint-Priest, France	EU/1/16/1129	Apvalkotās tabletes	J05AF07	12.12.2016.
12.12.2016.	OCALIVA	obetiholskābes	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	EU/1/16/1139	Apvalkotās tabletes	A05AA04	15.12.2016.
12.12.2016.	Rekovelle	delta folitropīna	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	emtricitabīns/tenofovīra disoproksils	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/16/1133	Apvalkotās tabletes	J05AR03	20.12.2016.

— **Tirdzniecības atļaujas grozīšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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, Espaňa	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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

— **Tirdzniecības atļaujas izņemšana no aprites** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. pants)

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 38. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	INN (starptautiskais nepatentētais nosaukums)	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Farmaceitiskā forma	AĶT kods (Anatomiski ķīmiski terapeitiskais kods)	Paziņojuma datums
13.12.2016.	Cepedex	deksmedetomidīns	CP Pharma Handelsgesellschaft mbH Ostlandring 13, D-31303 Burgdorf, Deutschland	EU/2/16/200	Šķīdums injekcijai	QN05CM18	15.12.2016.
13.12.2016.	Halagon	halofuginons	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/16/201	Šķīdums iekšķīgai lietošanai	QP51AX08	15.12.2016.

— **Tirdzniecības atļaujas grozīšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 38. pants): **pieņemtas**

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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.

Ikvienam, kurš vēlas apskatīt publisko novērtējuma ziņojumu par attiecīgajām zālēm un ar tām saistītos lēmumus, jāsazinās ar:

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom