IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2016. gada 1. jūnija līdz 2016. gada 30. jūnijam

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

(2016/C 277/01)

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

— **Tirdzniecības atļaujas izsniegšana** (Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 13. 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
21.6.2016.	Odefsey	emtricitabine/rilpivirīns/tenofovir alafenamide	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/16/1112	Apvalkotās tabletes	J05AR19	23.6.2016.
24.6.2016.	Ongentys	opikapons	Bial – Portela & C[a], SA À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/15/1066	Cietās kapsulas	Pending	28.6.2016.
24.6.2016.	Zavicefta	ceftazidīms/avibaktāms	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1109	Pulveris infūziju šķīduma koncentrāta pagatavošanai	J01DD52	28.6.2016.
29.6.2016.	Enzepi	Aizkuņģa dziedzera pulveris	APTALIS PHARMA SAS 5/6 Place de l'Iris – La Défense 5 92400 Courbevoie France	EU/1/16/1113	Zarnās šķīstošās cietās kapsulas	A09AA02	1.7.2016.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
24.6.2016.	Dropcys	Lucane Pharma 172 rue de Charonne, 75011 Paris, France		28.6.2016.

— **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
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.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
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 Paris, France	EU/1/06/376	23.6.2016.
21.6.2016.	Karvea	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, 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 Paris, 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.

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

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

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

— **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
1.6.2016.	Clopidogrel/Acetylsalicylic acid 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.

— **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
21.6.2016.	Sevocalm	sevoflurāns	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/16/196	Inhalācijas tvaiki, šķīdums	Pending	24.6.2016.

— **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
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.

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