IV

(Paziņojumi)

EIROPAS SAVIENĪBAS IESTĀŽU UN STRUKTŪRU SNIEGTI PAZIŅOJUMI

EIROPAS KOMISIJA

Eiropas Savienības lēmumu kopsavilkums par zāļu tirdzniecības atļaujām no 2017. gada 1. februāra līdz 28. februārim

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

(2017/C 102/01)

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

— **Tirdzniecības atļaujas izsniegšana** (13. pants Eiropas Parlamenta un Padomes Regulā (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
13.2.2017.	*LIFMIOR*	etanercepts	*Pfizer Limited* *Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom*	EU/1/16/1165	Pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	L04AB01	15.2.2017.
13.2.2017.	*Olumiant*	baricitinibs	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/16/1170	Apvalkotās tabletes	L04AA37	15.2.2017.
13.2.2017.	*Vihuma*	simoktokog alfa	*Octapharma AB* *Lars Forssells gata 23, 112 75 Stockholm, Sverige*	EU/1/16/1168	Pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	B02BD02	15.2.2017.
16.2.2017.	*Alecensa*	alektinibs	*Roche Registration Limited* *6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom*	EU/1/16/1169	Cietās kapsulas	L01XE36	20.2.2017.
17.2.2017.	*Truxima*	rituksimabs	*Celltrion Healthcare Hungary Kft.* *1051 Budapest Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország*	EU/1/16/1167	Koncentrāts infūziju šķīduma pagatavošanai	L01XC02	22.2.2017.
27.2.2017.	*Pregabalin Zentiva k.s*	pregabalīns	*Zentiva, k.s.* *U Kabelovny 130, 102 37 Praha 10, Česká republika*	EU/1/16/1166	Cietās kapsulas	N03AX16	1.3.2017.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
6.2.2017.	*Alimta*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/04/290	8.2.2017.
6.2.2017.	*Amyvid*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/12/805	8.2.2017.
6.2.2017.	*APTIVUS*	*Boehringer Ingelheim International GmbH* *Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland*	EU/1/05/315	8.2.2017.
6.2.2017.	*Gardasil*	*MSD VACCINS* *162 avenue Jean Jaurès, 69007 Lyon, France*	EU/1/06/357	8.2.2017.
6.2.2017.	*Imvanex*	*Bavarian Nordic A/S* *Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark*	EU/1/13/855	8.2.2017.
6.2.2017.	*Scintimun*	*CIS bio international* *Boîte postale 32, F-91192 Gif-sur-Yvette, France*	EU/1/09/602	8.2.2017.
6.2.2017.	*Silgard*	*Merck Sharp & Dohme Limited* *Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom*	EU/1/06/358	8.2.2017.
6.2.2017.	*Stribild*	*Gilead Sciences International Limited* *Cambridge CB21 6GT, United Kingdom*	EU/1/13/830	8.2.2017.
6.2.2017.	*Tolucombi*	*Krka, d. d., Novo Mesto* *Šmarješka cesta 6, 8501 Novo mesto, Slovenija*	EU/1/13/821	9.2.2017.
6.2.2017.	*Victrelis*	*Merck Sharp & Dohme Limited* *Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom*	EU/1/11/704	8.2.2017.
8.2.2017.	*Optruma*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/98/074	10.2.2017.
13.2.2017.	*Aripiprazole Zentiva*	*Zentiva, k.s.* *U Kabelovny 130, 102 37 Praha 10, Česká republika*	EU/1/15/1009	15.2.2017.
13.2.2017.	*Senshio*	*Shionogi Limited* *33 Kingsway, London WC2B 6UF, United Kingdom*	EU/1/14/978	15.2.2017.
13.2.2017.	*Sustiva*	*Bristol-Myers Squibb Pharma EEIG* *Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom*	EU/1/99/110	15.2.2017.
16.2.2017.	*Aripiprazole Sandoz*	*Sandoz GmbH* *Biochemiestrasse 10, A-6250 Kundl, Österreich*	EU/1/15/1029	20.2.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
16.2.2017.	*Armisarte*	*Actavis Group PTC ehf.* *Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland*	EU/1/15/1063	20.2.2017.
16.2.2017.	*Brimica Genuair*	*AstraZeneca AB* *SE-151 85 Södertälje, Sverige*	EU/1/14/963	20.2.2017.
16.2.2017.	*Docetaxel Teva*	*Teva B.V.* *Swensweg 5, 2031 GA Haarlem, Nederland*	EU/1/09/611	20.2.2017.
16.2.2017.	*Duaklir Genuair*	*AstraZeneca AB* *SE-151 85 Södertälje, Sverige*	EU/1/14/964	20.2.2017.
16.2.2017.	*Enyglid*	*Krka, d. d., Novo Mesto* *Šmarješka cesta 6, 8501 Novo mesto, Slovenija*	EU/1/09/580	20.2.2017.
16.2.2017.	*EVOTAZ*	*Bristol-Myers Squibb Pharma EEIG* *Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom*	EU/1/15/1025	20.2.2017.
16.2.2017.	*Farydak*	*Novartis Europharm Limited* *Frimley Business Park, Camberley GU16 7SR, United Kingdom*	EU/1/15/1023	20.2.2017.
16.2.2017.	*Forsteo*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/03/247	20.2.2017.
16.2.2017.	*Genvoya*	*Gilead Sciences International Limited* *Cambridge CB21 6GT, United Kingdom*	EU/1/15/1061	20.2.2017.
16.2.2017.	*INOmax*	*Linde Healthcare AB* *SE-181 81 Lidingö, Sverige*	EU/1/01/194	22.2.2017.
16.2.2017.	*Irbesartan/Hydrochlorothiazide Teva*	*Teva B.V.* *Swensweg 5, 2031 GA Haarlem, Nederland*	EU/1/09/583	20.2.2017.
16.2.2017.	*Kadcyla*	*Roche Registration Limited* *6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom*	EU/1/13/885	20.2.2017.
16.2.2017.	*Kalydeco*	*Vertex Pharmaceuticals (Europe) Limited* *2 Kingdom Street, London W2 6BD, United Kingdom*	EU/1/12/782	20.2.2017.
16.2.2017.	*Leganto*	*UCB Manufacturing Ireland Ltd* *Shannon Industrial Estate, Co, Clare, Ireland*	EU/1/11/695	20.2.2017.
16.2.2017.	*Mirapexin*	*Boehringer Ingelheim International GmbH* *Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland*	EU/1/97/051	20.2.2017.
16.2.2017.	*Neupro*	*UCB Manufacturing Ireland Ltd* *Shannon Industrial Estate, Co, Clare, Ireland*	EU/1/05/331	20.2.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
16.2.2017.	*Nimenrix*	*Pfizer Limited* *Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom*	EU/1/12/767	20.2.2017.
16.2.2017.	*Nonafact*	*Sanquin Plasma Products B.V.* *Plesmanlaan 125, NL-1066 CX Amsterdam, Nederland*	EU/1/01/186	20.2.2017.
16.2.2017.	*Nucala*	*GlaxoSmithKline Trading Services Limited* *Currabinny, Carrigaline, County Cork, Ireland*	EU/1/15/1043	20.2.2017.
16.2.2017.	*Optimark*	*Mallinckrodt Deutschland GmbH* *Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland*	EU/1/07/398	20.2.2017.
16.2.2017.	*Portrazza*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/15/1084	20.2.2017.
16.2.2017.	*Quinsair*	*Horizon Pharma Europe B.V.* *Naritaweg 165, NL-1043 BW Amsterdam, Nederland*	EU/1/14/973	20.2.2017.
16.2.2017.	*Ravicti*	*Horizon Pharma Ireland Limited* *Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland*	EU/1/15/1062	20.2.2017.
16.2.2017.	*Repaglinide Krka*	*Krka, d. d., Novo Mesto* *Šmarješka cesta 6, 8501 Novo mesto, Slovenija*	EU/1/09/579	20.2.2017.
16.2.2017.	*Revlimid*	*Celgene Europe Limited* *1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom*	EU/1/07/391	20.2.2017.
16.2.2017.	*Revolade*	*Novartis Europharm Limited* *Frimley Business Park, Camberley GU16 7SR, United Kingdom*	EU/1/10/612	20.2.2017.
16.2.2017.	*Rivastigmine Actavis*	*Actavis Group PTC ehf.* *Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland*	EU/1/11/693	20.2.2017.
16.2.2017.	*Sifrol*	*Boehringer Ingelheim International GmbH* *Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland*	EU/1/97/050	20.2.2017.
16.2.2017.	*Stocrin*	*Merck Sharp & Dohme Limited* *Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom*	EU/1/99/111	20.2.2017.
16.2.2017.	*Twynsta*	*Boehringer Ingelheim International GmbH* *Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland*	EU/1/10/648	20.2.2017.
16.2.2017.	*Viread*	*Gilead Sciences International Limited* *Cambridge CB21 6GT, United Kingdom*	EU/1/01/200	20.2.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
16.2.2017.	*Zyprexa Velotab*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/99/125	20.2.2017.
17.2.2017.	*Caprelsa*	*Genzyme Europe B.V.* *Gooimeer 10, NL-1411 DD Naarden, Nederland*	EU/1/11/749	21.2.2017.
17.2.2017.	*Cyramza*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/14/957	21.2.2017.
17.2.2017.	*Emend*	*Merck Sharp & Dohme Limited* *Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom*	EU/1/03/262	21.2.2017.
17.2.2017.	*IMBRUVICA*	*Janssen-Cilag International NV* *Turnhoutseweg 30, B-2340 Beerse, België*	EU/1/14/945	21.2.2017.
17.2.2017.	*Pioglitazone Teva*	*Teva B.V.* *Swensweg 5, 2031 GA Haarlem, Nederland*	EU/1/12/757	21.2.2017.
17.2.2017.	*Pioglitazone Teva Pharma*	*Teva B.V.* *Swensweg 5, 2031 GA Haarlem, Nederland*	EU/1/12/758	21.2.2017.
17.2.2017.	*Repatha*	*Amgen Europe B.V.* *Minervum 7061, NL-4817 ZK Breda, Nederland*	EU/1/15/1016	21. 2.2017.
23.2.2017.	*Dacogen*	*Janssen-Cilag International NV* *Turnhoutseweg 30, B-2340 Beerse, België*	EU/1/12/792	27.2.2017.
23.2.2017.	*Daklinza*	*Bristol-Myers Squibb Pharma EEIG* *Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom*	EU/1/14/939	27.2.2017.
23.2.2017.	*Docetaxel Accord*	*Accord Healthcare Limited* *Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom*	EU/1/12/769	27.2.2017.
23.2.2017.	*Docetaxel Kabi*	*Fresenius Kabi Oncology Plc.* *Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom*	EU/1/12/770	27.2.2017.
23.2.2017.	*Exviera*	*AbbVie Ltd* *Maidenhead, SL6 4UB, United Kingdom*	EU/1/14/983	27.2.2017.
23.2.2017.	*Harvoni*	*Gilead Sciences International Limited* *Cambridge CB21 6GT, United Kingdom*	EU/1/14/958	27.2.2017.
23.2.2017.	*Ilaris*	*Novartis Europharm Limited* *Frimley Business Park, Camberley GU16 7SR, United Kingdom*	EU/1/09/564	27.2.2017.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
23.2.2017.	*Ketoconazole HRA*	*Laboratoire HRA Pharma* *15 rue Béranger, F-75003 Paris, France*	EU/1/14/965	27.2.2017.
23.2.2017.	*Lamivudine Teva*	*Teva B.V.* *Swensweg 5, 2031 GA Haarlem, Nederland*	EU/1/09/566	27.2.2017.
23.2.2017.	*OLYSIO*	*Janssen-Cilag International NV* *Turnhoutseweg 30, B-2340 Beerse, België*	EU/1/14/924	27.2.2017.
23.2.2017.	*Revlimid*	*Celgene Europe Limited* *1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom*	EU/1/07/391	27.2.2017.
23.2.2017.	*Sovaldi*	*Gilead Sciences International Limited* *Cambridge CB21 6GT, United Kingdom*	EU/1/13/894	27.2.2017.
23.2.2017.	*Tivicay*	*ViiV Healthcare UK Limited* *980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom*	EU/1/13/892	27.2.2017.
23.2.2017.	*Vargatef*	*Boehringer Ingelheim International GmbH* *Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland*	EU/1/14/954	27.2.2017.
23.2.2017.	*Viekirax*	*AbbVie Ltd* *Maidenhead, SL6 4UB, United Kingdom*	EU/1/14/982	27.2.2017.
23.2.2017.	*Zinforo*	*AstraZeneca AB* *SE-151 85 Södertälje, Sverige*	EU/1/12/785	27.2.2017.
27.2.2017.	*Adcirca*	*Eli Lilly Nederland B.V.* *Papendorpseweg 83, 3528 BJ Utrecht, Nederland*	EU/1/08/476	1.3.2017.
27.2.2017.	*Kisplyx*	*Eisai Europe Limited* *European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom*	EU/1/16/1128	1.3.2017.
27.2.2017.	*Vectibix*	*Amgen Europe B.V.* *Minervum 7061, NL-4817 ZK Breda, Nederland*	EU/1/07/423	1.3.2017.

— **Tirdzniecības atļaujas izsniegšana** (38. pants Eiropas Parlamenta un Padomes Regulā (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
2.2.2017.	*VarroMed*	skābeņskābes dihidrāts/skudrskābe	*BeeVital GmbH* *Wiesenbergstrasse 19, 5164, Seeham, Österreich*	EU/2/16/203	Bišu stropa dispersija	*Pending*	6.2.2017.
9.2.2017.	*Stronghold Plus*	Selamektīns/sarolaners	*Zoetis Belgium S.A.* *Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique*	EU/2/16/204	Spot-on šķīdums	QP54AA55	13.2.2017.

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

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
9.2.2017.	*EQUIOXX*	*Merial* *29 avenue Tony Garnier, F-69007 Lyon, France*	EU/2/08/083	13.2.2017.
10.2.2017.	*Vectormune ND*	*CEVA-Phylaxia Co. Ltd.* *Budapest, Szállás u. 5, 1107 MAGYARORSZÁG*	EU/2/15/188	14.2.2017.
17.2.2017.	*ERYSENG PARVO*	*Laboratorios Hipra, S.A.* *Avda. La Selva, 135, E-17170- Amer (Girona), España*	EU/2/14/167	21.2.2017.
17.2.2017.	*Trifexis*	*Eli Lilly and Company Ltd, Elanco Animal Health Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom*	EU/2/13/155	21.2.2017.
17.2.2017.	*Vectra 3D*	*CEVA SANTE ANIMALE* *10 avenue de la Ballastière, F-33500 Libourne, France*	EU/2/13/156	21.2.2017.
27.2.2017.	*Equip WNV*	*Zoetis Belgium S.A.* *Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique*	EU/2/08/086	1.3.2017.

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