

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

EUROPEAN COMMISSION

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 June 2016 to 30 June 2016**

*(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of
the Council⁽¹⁾)*

(2016/C 277/01)

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

— Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
21.6.2016	Odefsey	emtricitabine/rilpivirine/tenofovir alafenamide	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/16/1112	Film-coated tablet	J05AR19	23.6.2016
24.6.2016	Ongentys	opicapone	Bial — Portela & C ^a , SA A Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/15/1066	Capsule, hard	Pending	28.6.2016
24.6.2016	Zavicefta	ceftazidime/avibactam	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1109	Powder for concentrate for solution for infusion	J01DD52	28.6.2016
29.6.2016	Enzepi	pancreas powder	APTALIS PHARMA SAS 5/6 Place de l'Iris — La Défense 5 92400 Courbevoie France	EU/1/16/1113	Capsule, hard, gastro-resistant	A09AA02	1.7.2016

— **Issuing of a marketing authorization** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Rejected**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
24.6.2016	Dropcys	Lucane Pharma 172 rue de Charonne, 75011 Paris, France		28.6.2016

— **Modification of a marketing authorization** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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	Adrovanse	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 Co- lombes 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 ratio-pharm GmbH	Archie Samuel s.r.o. Slunná 16, CZ-61700 Brno, Česká republika	EU/1/09/541	6.6.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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, Ux- bridge 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, Ux- bridge UB8 1DH, United Kingdom	EU/1/14/939	28.6.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

— **Withdrawal of a marketing authorization** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

— **Issuing of a marketing authorization** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
21.6.2016	Sevocalm	sevoflurane	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/16/196	Inhalation vapour, liquid	Pending	24.6.2016

— **Modification of a marketing authorization** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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 Kingdom	EU/2/08/090	29.6.2016

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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