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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 May 2015 to 31 May 2015

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

(2015/C 211/01)

([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
6.5.2015	Zykadia	ceritinib	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/999	Capsule, hard	L01XE	8.5.2015
27.5.2015	Akynzeo	netupitant/palonosetron	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	Capsule, hard	A04AA55	29.5.2015
27.5.2015	Jinarc	tolvaptan	Otsuka Pharmaceutical Europe Ltd Gallions, Wexham Springs, Framewood Road, Wexham, SL3 6PJ, United Kingdom	EU/1/15/1000	Tablet	Pending	29.5.2015
27.5.2015	Synjardy	empagliflozin/metformin	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	Film-coated tablet	A10BD20	29.5.2015
27.5.2015	Voriconazole Hospira	voriconazole	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/15/1004	Powder for solution for infusion	J02AC03	29.5.2015
28.5.2015	Lenvima	lenvatinib	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/15/1002	Capsule, hard	L01XE29	1.6.2015

— **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
5.5.2015	Copalia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/372	7.5.2015
5.5.2015	Copalia HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/575	7.5.2015
5.5.2015	Dafiro	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/371	7.5.2015
5.5.2015	Dafiro HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/574	7.5.2015
5.5.2015	Erivedge	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/848	8.5.2015
5.5.2015	Exforge	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/370	7.5.2015
5.5.2015	Exforge HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/569	7.5.2015
5.5.2015	Imprida	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/373	7.5.2015
5.5.2015	INCRELEX	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/07/402	7.5.2015
5.5.2015	Irbesartan/Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	8.5.2015
5.5.2015	Orfadin	Swedish Orphan Biovitrum International AB SE-112 76 Stockholm, Sverige	EU/1/04/303	8.5.2015
5.5.2015	Sycrest	Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland	EU/1/10/640	7.5.2015
5.5.2015	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222	8.5.2015
5.5.2015	Telzir	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/282	7.5.2015
5.5.2015	Tyverb	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/440	7.5.2015

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
5.5.2015	Voncento	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/13/857	7.5.2015
5.5.2015	Votrient	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/628	7.5.2015
5.5.2015	Zoledronic acid Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/772	7.5.2015
5.5.2015	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/479	7.5.2015
6.5.2015	Arzerra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/625	8.5.2015
6.5.2015	Celsentri	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/07/418	8.5.2015
6.5.2015	Celvapan	Baxter AG Industriestraße 67, A-1221 Wien, Österreich	EU/1/08/506	8.5.2015
6.5.2015	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	8.5.2015
6.5.2015	Imatinib Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/808	8.5.2015
6.5.2015	Optaflu	Novartis Influenza Vaccines Marburg GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/07/394	8.5.2015
6.5.2015	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	8.5.2015
6.5.2015	Tafinlar	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/13/865	8.5.2015
13.5.2015	Cayston	Gilead Sciences International Limited Granta Park, Abington, Cambridge CB21 6GT, United Kingdom	EU/1/09/543	19.5.2015
13.5.2015	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	19.5.2015
13.5.2015	Granupas	Lucane Pharma 172 rue de Charonne, 75011 Paris, France	EU/1/13/896	19.5.2015

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
13.5.2015	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	19.5.2015
13.5.2015	Leflunomide ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/10/654	19.5.2015
13.5.2015	Luminity	Lantheus MI UK Limited Festival House, 39 Oxford Street, Newbury, Berkshire RG14 1JG, United Kingdom	EU/1/06/361	19.5.2015
13.5.2015	Memantine Merz	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/12/799	19.5.2015
13.5.2015	Ovitrelle	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/165	19.5.2015
13.5.2015	Trizivir	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/00/156	19.5.2015
13.5.2015	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	19.5.2015
13.5.2015	Vyndaqel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/11/717	19.5.2015
27.5.2015	Aflunov	Novartis Vaccines Influenza S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/658	29.5.2015
27.5.2015	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/283	29.5.2015
27.5.2015	Brinavess	Cardiome UK Limited Lakeside House, 1 Furzeground Way, Stockley Park, Uxbridge, Middlesex, UB11 1BD, United Kingdom	EU/1/10/645	29.5.2015
27.5.2015	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, D-27472 Cuxhaven, Deutschland	EU/1/09/555	29.5.2015
27.5.2015	Cometriq	TMC Pharma Services Ltd Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, Hampshire RG27 8AS, United Kingdom	EU/1/13/890	29.5.2015
27.5.2015	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/296	29.5.2015

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
27.5.2015	Erivedge	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/848	29.5.2015
27.5.2015	Esmya	Gedeon Richter Plc. Gyömrői út 19-21., H-1103 Budapest, Magyarország	EU/1/12/750	29.5.2015
27.5.2015	Foclivia	Novartis Vaccines Influenza S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/09/577	29.5.2015
27.5.2015	Gardasil	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	29.5.2015
27.5.2015	Imnovid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/13/850	29.5.2015
27.5.2015	INCRELEX	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/07/402	29.5.2015
27.5.2015	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	29.5.2015
27.5.2015	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278	29.5.2015
27.5.2015	Levetiracetam Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/11/712	29.5.2015
27.5.2015	Myclausen	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, D-14167 Berlin, Deutschland	EU/1/10/647	29.5.2015
27.5.2015	Nexium Control	Pfizer Consumer Healthcare Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/13/860	29.5.2015
27.5.2015	Nivestim	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/631	29.5.2015
27.5.2015	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/453	29.5.2015
27.5.2015	Raloxifene Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/627	29.6.2015
27.5.2015	Relistor	TMC Pharma Services Ltd Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, Hampshire RG27 8AS, United Kingdom	EU/1/08/463	29.5.2015

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
27.5.2015	Resolor	Shire Pharmaceuticals Ireland Limited 5 River Walk, Citywest Business Campus, Dublin 24, Ireland	EU/1/09/581	29.5.2015
27.5.2015	Selincro	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/12/815	29.5.2015
27.5.2015	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358	29.5.2015
27.5.2015	Sonata	Meda AB Pipers väg 2A, S-170 09 Solna, Sverige	EU/1/99/102	29.5.2015
27.5.2015	Sovaldi	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/894	29.5.2015
27.5.2015	Targretin	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire AL10 9SN, United Kingdom	EU/1/01/178	29.5.2015
27.5.2015	Temodal	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/98/096	29.5.2015
27.5.2015	Temozolomide Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/10/615	29.5.2015
27.5.2015	Thalidomide Celgene	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/08/443	29.5.2015
27.5.2015	Tolucombi	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/821	29.5.2015
27.5.2015	Volibris	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/08/451	29.5.2015
27.5.2015	Xeristar	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/297	29.5.2015
27.5.2015	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/13/846	29.5.2015
27.5.2015	Yentreve	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/280	29.5.2015
27.5.2015	Yondelis	Pharma Mar S.A. Avda de los Reyes 1, Polígono Industrial La Mina, E-28770 Colmenar Viejo, Madrid, España	EU/1/07/417	29.5.2015

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
28.5.2015	Aclasta	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/05/308	1.6.2015
28.5.2015	alli	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/401	1.6.2015
28.5.2015	Dificlir	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/11/733	1.6.2015
28.5.2015	Invega	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/07/395	1.6.2015
28.5.2015	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383	1.6.2015
28.5.2015	Lonquex	UAB 'Sicor Biotech' Molėtų pl. 5, LT-08409 Vilnius, Lietuva	EU/1/13/856	1.6.2015
28.5.2015	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	1.6.2015
28.5.2015	Topotecan Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633	1.6.2015
28.5.2015	Tygacil	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/06/336	1.6.2015

— **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
5.5.2015	Clopidogrel DURA	Mylan dura GmbH Wittichstraße 6, D-64295 Darmstadt, Deutschland	EU/1/09/560	7.5.2015
6.5.2015	Provenge	Dendreon UK Limited 41 Chalton Street, London NW1 1JD, United Kingdom	EU/1/13/867	8.5.2015

— **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
5.5.2015	MS-H vaccine	Pharmsure International Ltd Unit 28, Moorlands Trading Estate, Moor Lane, Metheringham Lincolnshire, LN4 3HX, United Kingdom	EU/2/11/126	7.5.2015
5.5.2015	Purevax RCP	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/04/052	7.5.2015

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
13.5.2015	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/98/006	19.5.2015
13.5.2015	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	19.5.2015
27.5.2015	Meloxivet	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/07/077	29.5.2015
27.5.2015	Purevax FeLV	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/00/019	29.5.2015
27.5.2015	Purevax RCPCh	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/04/050	29.5.2015
27.5.2015	Suprelorin	VIRBAC S.A. 1ère Avenue — 2065 m — L.I.D., F-06516 Carros Cedex, France	EU/2/07/072	29.5.2015

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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