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 2012 to 31 May 2012

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

(2012/C 190/01)

[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
7.5.2012	Riluzole Zentiva	Riluzole	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/12/768/001	Film-coated tablet	N07XX02	10.5.2012
10.5.2012	Pixuvri	pixantrone	CTI Life Sciences Ltd Biopark, Broadwater Road, Welwyn Garden City, Hertfordshire AL73AX, United Kingdom	EU/1/12/764/001	powder for concentrate for solution for infusion	L01DB11	14.5.2012
22.5.2012	Docetaxel Accord	Docetaxel	Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF United Kingdom	EU/1/12/769/001-003	Concentrate for solution for infusion	L01CD02	25.5.2012
22.5.2012	Docetaxel Kabi	Docetaxel	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire, GU35 0NF, United Kingdom	EU/1/12/770/001-004	Concentrate for solution for infusion	L01CD02	25.5.2012

— **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
7.5.2012	Intanza	Sanofi Pasteur MSD SNC 8, rue Jonas Salk, Lyon 69007, France	EU/1/08/505/001-003	9.5.2012
7.5.2012	Ovitrelle	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/165/001-003	9.5.2012
10.5.2012	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1HU, United Kingdom	EU/1/04/276/001-020 EU/1/04/276/024-036	14.5.2012
10.5.2012	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/086/001-034	14.5.2012
10.5.2012	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/642/001-004	14.5.2012
10.5.2012	Irbesartan / Hydrochlorothiazide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/583/001-072	14.5.2012
10.5.2012	Siklos	ADDMEDICA 101, rue Saint Lazare, Paris 75009, France	EU/1/07/397/001-004	14.5.2012
10.5.2012	Telmisartan Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76 78, 220 Hafnarfjörður, Iceland	EU/1/10/639/001-030	14.5.2012
10.5.2012	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/610/001-060	14.5.2012
10.5.2012	Trobalt	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/681/001-013	14.5.2012
14.5.2012	Brilique	AstraZeneca AB Södertälje S 151 85, Sverige	EU/1/10/655/001-006	16.5.2012
14.5.2012	Invega	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse – België	EU/1/07/395/001-095	16.5.2012

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
14.5.2012	JEVTANA	SANOFI 174, avenue de France, F-75013 Paris, France	EU/1/11/676/001	16.5.2012
14.5.2012	Luveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/155/001-003	16.5.2012
14.5.2012	Possia	AstraZeneca AB Södertälje S 151 85, Sverige	EU/1/10/656/001-006	16.5.2012
14.5.2012	TOBI Podhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/10/652/001-003	16.5.2012
15.5.2012	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/008-013 EU/1/07/400/017-024	17.5.2012
15.5.2012	Topotecan Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633/001-002	17.5.2012
15.5.2012	Vizarsin	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/551/001-027	17.5.2012
22.5.2012	Aerinaze	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/399/001-006	25.5.2012
22.5.2012	Fampyra	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/11/699/001-004	25.5.2012
22.5.2012	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-008 EU/1/06/357/018-021	25.5.2012
22.5.2012	HALAVEN	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertsforshire AL10 9SN, United Kingdom	EU/1/11/678/001-002	25.5.2012
22.5.2012	Hizentra	CSL Behring GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland	EU/1/11/687/001-012	25.5.2012

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
22.5.2012	IDflu	Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France	EU/1/08/507/001-003	25.5.2012
22.5.2012	Pergoveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/07/396/001-003	25.5.2012
22.5.2012	Silgard	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358/001-008 EU/1/06/358/018-021	25.5.2012
22.5.2012	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-005	24.5.2012
22.5.2012	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-005	25.5.2012
22.5.2012	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	25.5.2012
25.5.2012	Benlysta	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/700/001-002	30.5.2012
25.5.2012	Betaferon	Bayer Pharma AG D - 13342 Berlin, Deutschland	EU/1/95/003/003-012	30.5.2012
25.5.2012	Busilvex	Pierre Fabre Médicament 45, Place Abel Gance, 92654 Boulogne Billancourt Cedex, France	EU/1/03/254/002	31.5.2012
25.5.2012	Clopidogrel Teva Pharma B.V.	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/649/001-016	30.5.2012
25.5.2012	Conbriza	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/511/001-005	31.5.2012
25.5.2012	DuoCover	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/10/623/001-015	30.5.2012

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
25.5.2012	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416/001-002	31.5.2012
25.5.2012	Fosavance	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/310/001-009	30.5.2012
25.5.2012	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/576/001-039	30.5.2012
25.5.2012	Ixiaro	Intercell AG Campus Vienna Biocenter 3 A-1030 Wien, Österreich	EU/1/08/501/001-002	31.5.2012
25.5.2012	Keppra	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/00/146/001-032	1.6.2012
25.5.2012	Kinzalkomb	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/02/214/001-015	31.5.2012
25.5.2012	Kinzalmono	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/98/091/001-014	31.5.2012
25.5.2012	Kuvan	Merck Serono Europe Limited 56 Marsh Wall, London E14 9TP, United Kingdom	EU/1/08/481/001-003	30.5.2012
25.5.2012	Lamivudine / Zidovudine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/663/001-002	1.6.2012
25.5.2012	Micardis	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090/001-022	31.5.2012
25.5.2012	MicardisPlus	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/02/213/001-023	31.5.2012
25.5.2012	Neulasta	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/02/227/001-002 EU/1/02/227/004	1.6.2012

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
25.5.2012	Nevirapine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/598/001-004	30.5.2012
25.5.2012	Onduarp	Boehringer Ingelheim International GmbH Binger Str. 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729/001-006	30.5.2012
25.5.2012	Optaflu	Novartis Vaccines and Diagnostics GmbH Emil-von-Behring-Strasse 76, D-35041 Marburg, Deutschland	EU/1/07/394/001-009	31.5.2012
25.5.2012	Osseor	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/287/001-006	30.5.2012
25.5.2012	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	1.6.2012
25.5.2012	Pritor	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/98/089/001-022	30.5.2012
25.5.2012	PritorPlus	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/02/215/001-021	30.5.2012
25.5.2012	Protelos	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/288/001-006	
25.5.2012	Rasilamlo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/686/001-056	30.5.2012
25.5.2012	Rasilez	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	30.5.2012
25.5.2012	Rasilez HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	31.5.2012
25.5.2012	Rasitrio	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/730/001-060	31.5.2012

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
25.5.2012	Riprazo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-040	30.5.2012
25.5.2012	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	1.6.2012
25.5.2012	Rivastigmine Actavis	Actavis Group PTC ehf. ReykjavÍkurvegur 76-78, Hafnarfjörður 220, Iceland	EU/1/11/693/001-016	1.6.2012
25.5.2012	RoActemra	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	31.5.2012
25.5.2012	Sprimeo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-040	31.5.2012
25.5.2012	Sprimeo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/683/001-080	1.6.2012
25.5.2012	Temozolomide Hospira	Hospira UK Ltd. Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/615/001-002 EU/1/10/615/005-006 EU/1/10/615/009-010 EU/1/10/615/013-014 EU/1/10/615/017-018 EU/1/10/615/021-022	31.5.2012
25.5.2012	Tysabri	Elan Pharma International Ltd. Treasury Building, Lower Grand Canal Street, Dublin 2, IRELAND	EU/1/06/346/001	31.5.2012
25.5.2012	Vantavo	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572/001-004 EU/1/09/572/006-008	30.5.2012
25.5.2012	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	31.5.2012

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
25.5.2012	Vistide	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/97/037/001	31.5.2012
25.5.2012	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	30.5.2012
25.5.2012	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	31.5.2012
25.5.2012	Xolair	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/319/001-010	30.5.2012
31.5.2012	Lamivudine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/566/001-005	4.6.2012
31.5.2012	Peyona	CHIESI FARMACEUTICI SpA Via Palermo 26/A, I-43100 Parma, ITALIA	EU/1/09/528/001-002	4.6.2012
31.5.2012	Temozolomide Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/09/606/001-012	4.6.2012

— **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
10.5.2012	Valtropin	BioPartners GmbH Kaiserpassage 11 - D-72764 Reutlingen, Deutschland	EU/1/06/335/001	14.5.2012
25.5.2012	Docefrez	Sun Pharmaceuticals Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/10/630/001-002	31.5.2012
25.5.2012	Intrinsa	Warner Chilcott UK Ltd Old Belfast Road, Millbrook, Larne, County Antrim BT40 2SH, United Kingdom	EU/1/06/352/001-003	31.5.2012

— **Lift of suspension of a marketing authorization (Article 20 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
25.5.2012	Angiox	The Medicines Company UK Ltd 115 L Milton Park, Abingdon, Oxfordshire, OX14 4SA, United Kingdom	EU/1/04/289/001	31.5.2012
25.5.2012	Caelyx	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/96/011/001-004	31.5.2012
25.5.2012	Luminity	Lantheus MI UK Limited Festival House - 39 Oxford Street - Newbury - Berkshire RG14 1JG - United Kingdom	EU/1/06/361/001-002	31.5.2012
25.5.2012	Mepact	IDM PHARMA SAS 11-15 quai De Dion Bouton, 92816 Puteaux Cedex, France	EU/1/08/502/001	1.6.2012
25.5.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	31.5.2012
25.5.2012	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/07/424/001	30.5.2012
25.5.2012	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	31.5.2012
31.5.2012	Ceplene	EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland	EU/1/08/477/001	4.6.2012

— **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
10.5.2012	Circovac	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/07/075/001-004	14.5.2012
10.5.2012	Netvax	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/09/093/001-002	14.5.2012
22.5.2012	Convenia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/06/059/001-002	30.5.2012
22.5.2012	Equip WNV	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/08/086/001-003	25.5.2012

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
22.5.2012	PRILACTONE	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/07/074/001-006	25.5.2012
25.5.2012	Onsior	Novartis Animal Health UK Ltd Frimley Business Park, Frimley/Camberley, Surrey, GU16 7SR, United Kingdom	EU/2/08/089/001-021	1.6.2012
25.5.2012	Suprelorin	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros – France	EU/2/07/072/001-004	1.6.2012

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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