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 March 2012 to 31 March 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 124/01)

[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
9.3.2012	Mercaptopurine Nova Laboratories	Mercaptopurine	Nova Laboratories Limited Martin House, Gloucester Crescent, Wigston Leicester, LE18 4YL, United Kingdom	EU/1/11/727/001	Oral suspension	L01BB02	13.3.2012
9.3.2012	Sepioglin	pioglitazone	Vaia S.A. 1, 28 Octovriou str., Ag. Varvara 123 51, Athens, Ελλάδα	EU/1/12/754/001-021	Tablet	A10BG03	13.3.2012
15.3.2012	Pioglitazone Actavis	pioglitazone	Actavis Group PTC ehf. Reykjavíkurvegi 76 78, 220 Hafnarfjörður, Iceland	EU/1/12/755/001-027	Tablet	A10BG03	20.3.2012
15.3.2012	Pioglitazone Actavis Group	pioglitazone	Actavis Group PTC ehf. Reykjavíkurvegi 76 - 78, 220 Hafnarfjörður, Iceland	EU/1/12/756/001-027	Tablet	A10BG03	20.3.2012
21.3.2012	Paglitaz	pioglitazone	KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/721/001-021	Tablet	A10BG03	26.3.2012
21.3.2012	Pioglitazone Accord	pioglitazone	Accord Healthcare Limited 5th Floor Charles House, 108/110 Finchley road, London NW3 5JJ, United Kingdom	EU/1/11/722/001-030	Tablet	A10BG03	27.3.2012
26.3.2012	Pioglitazone Teva	pioglitazone	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/12/757/001-030	Tablet	A10BG03	29.3.2012
26.3.2012	Pioglitazone Teva Pharma	pioglitazone	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/12/758/001-030	Tablet	A10BG03	29.3.2012

— **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
2.3.2012	ATryn	GTC Biotherapeutics UK Limited 10 Norwich Street, London EC4A 1BD, United Kingdom	EU/1/06/355/001-003	6.3.2012
2.3.2012	Daliresp	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/11/668/001-003	6.3.2012
2.3.2012	Esbriet	InterMune UK Ltd Euston Tower, Floor 32, 286 Euston Road, London, NW1 3DP, United Kingdom	EU/1/11/667/001-004	6.3.2012
2.3.2012	Fampyra	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/11/699/001-004	6.3.2012
2.3.2012	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026/001-002	6.3.2012
2.3.2012	Leflunomide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/675/001-010	6.3.2012
2.3.2012	Libertek	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/11/666/001-003	6.3.2012
2.3.2012	NutropinAq	Ipsen Pharma 65, quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/00/164/003-005	6.3.2012
2.3.2012	Ruconest	Pharming Group N.V. Darwinweg 24, NL-2333 CR Leiden, Nederland	EU/1/10/641/001	6.3.2012
2.3.2012	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/06/366/005-022	6.3.2012
2.3.2012	Valtropin	BioPartners GmbH Kaiserpassage 11 – D-72764 Reutlingen, Deutschland	EU/1/06/335/001	6.3.2012

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
6.3.2012	Clopidogrel Acino	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/532/001-007	8.3.2012
6.3.2012	Repso	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/674/001-010	8.3.2012
6.3.2012	Rivastigmine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/513/001-020	8.3.2012
6.3.2012	Topotecan Actavis	Actavis Group PTC ehf Reykjavikurvegur 76-78, 220 Hafnarfjordur, Iceland	EU/1/09/536/001-004	8.3.2012
8.3.2012	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/07/384/003-005	12.3.2012
8.3.2012	Firazyr	Shire Orphan Therapies GmbH Friedrichstrasse 149, D-10117 Berlin, Deutschland	EU/1/08/461/001-002	12.3.2012
8.3.2012	Pritor	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/98/089/001-022	12.3.2012
8.3.2012	PritorPlus	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/02/215/001-021	12.3.2012
9.3.2012	Samsca	Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1HU, United Kingdom	EU/1/09/539/001-004	13.3.2012
15.3.2012	Avamys	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/434/001-003	19.3.2012
15.3.2012	Carbaglu	Orphan Europe Immeuble Le Wilson, 70 Avenue du General de Gaulle, 92800 Puteaux, France	EU/1/02/246/001-003	19.3.2012
15.3.2012	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389/001-003	19.3.2012
15.3.2012	Prolia	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	19.3.2012

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
15.3.2012	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386/001-018	19.3.2012
15.3.2012	Ventavis	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/255/001-008	19.3.2012
15.3.2012	Vizarsin	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/551/001-012	19.3.2012
19.3.2012	Afinitor	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538/001-008	21.3.2012
19.3.2012	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118/001-010	21.3.2012
19.3.2012	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	22.3.2012
19.3.2012	Benlysta	Glaxo Group Limited Glaxo Wellcome House, Berkely Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/700/001-002	21.3.2012
19.3.2012	Byetta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/06/362/001-004	22.3.2012
19.3.2012	Fasturtec	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/00/170/001-002	21.3.2012
19.3.2012	Helixate NexGen	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/00/144/001-005	22.3.2012
19.3.2012	IDflu	Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France	EU/1/08/507/001-006	22.3.2012
19.3.2012	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720/001-002	21.3.2012
19.3.2012	Intanza	Sanofi Pasteur MSD SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/08/505/001-006	21.3.2012

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
19.3.2012	Intelence	Janssen-Cilag International NV Turnhoutseweg, 30 – 2340 Beerse – België	EU/1/08/468/001-002	21.3.2012
19.3.2012	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436/001-002	21.3.2012
19.3.2012	Kogenate Bayer	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/143/004-013	22.3.2012
19.3.2012	Leflunomide Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/09/604/001-010	21.3.2012
19.3.2012	Levitra	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/248/001-023	21.3.2012
19.3.2012	Norvir	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/96/016/001 EU/1/96/016/003-008	21.3.2012
19.3.2012	PegIntron	Schering Plough Europe Clos du Lynx 5, 1200 Bruxelles, Belgique – Lynx Binnenhof 5, 1200 Brussel, België	EU/1/00/131/001-050	21.3.2012
19.3.2012	Prevenar 13	Wyeth-Lederle Vaccines S.A. Pleinlaan 17 Boulevard de la Plaine, 1050 Brussel - Bruxelles, België-Belgique	EU/1/09/590/001-006	22.3.2012
19.3.2012	Privigen	CSL Behring GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland	EU/1/08/446/001-006	21.3.2012
19.3.2012	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	21.3.2012
19.3.2012	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	EU/1/08/462/001-012	22.3.2012
19.3.2012	Refludan	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/97/035/001-004	21.3.2012

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
19.3.2012	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	22.3.2012
19.3.2012	Resolor	Shire-Movetis NV Veedjik 58, B-2300 Turnhout, België	EU/1/09/581/001-008	21.3.2012
19.3.2012	Tasmar	Meda AB Pipers väg 2A, 170 09 Solna, Sverige	EU/1/97/044/001-009	21.3.2012
19.3.2012	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef, 60, 1070 Brussel, België	EU/1/08/470/001-013 EU/1/08/470/016-017	22.3.2012
19.3.2012	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	22.3.2012
21.3.2012	Atriance	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/403/001	26.3.2012
21.3.2012	Champix	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/360/001-013	26.3.2012
21.3.2012	Clopidogrel Krka d.d.	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562/001-009	26.3.2012
21.3.2012	Foclivia	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/09/577/001-004	26.3.2012
21.3.2012	Integrilin	Glaxo Group Ltd Greenford, Middlesex, UB6 ONN, United Kingdom	EU/1/99/109/001-002	23.3.2012
21.3.2012	Rapiscan	Rapidscan Pharma Solutions EU Ltd. Regent's Place, 338 Euston Road, London NW1 3BT, UK	EU/1/10/643/001	23.3.2012
21.3.2012	Revatio	Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/05/318/001-003	26.3.2012

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
21.3.2012	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498/001-008	26.3.2012
21.3.2012	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	26.3.2012
21.3.2012	Victrelis	Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom	EU/1/11/704/001-002	23.3.2012
21.3.2012	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	26.3.2012
21.3.2012	Xgeva	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/11/703/001-003	23.3.2012
21.3.2012	Zostavax	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/341/001-013	23.3.2012
26.3.2012	Azilect	Teva Pharma GmbH Graf-Arco-Str. 3, 89079 Ulm, Deutschland	EU/1/04/304/001-007	28.3.2012
26.3.2012	Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A Viale Shakespeare 47, 00144 Rome, Italia	EU/1/11/716/001-005	28.3.2012
26.3.2012	Neupro	Schwarz Pharma Ltd Shannon, Industrial Estate, Co.Clare, Ireland	EU/1/05/331/001-055	28.3.2012
26.3.2012	Nimvastid	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/525/001-050	28.3.2012
26.3.2012	Pandemic influenza vaccine H5N1 BAXTER	Baxter AG Industriestraße 67, A – 1221 Wien, Österreich	EU/1/09/571/001-002	28.3.2012
26.3.2012	PegIntron	Schering Plough Europe Clos du Lynx 5, 1200 Bruxelles, Belgique – Lynx Binnenhof 5, 1200 Brussel, België	EU/1/00/131/001-050	28.3.2012

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
26.3.2012	Plenadren	DuoCort Pharma AB Kullagatan 8-10, S-252 20 Helsingborg, Sverige	EU/1/11/715/001-002	28.3.2012
26.3.2012	Valdoxan	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes, Cedex, France	EU/1/08/499/001-008	28.3.2012
26.3.2012	ViraferonPeg	Schering Plough Europe Clos du Lynx 5, 1200 Bruxelles, Belgique – Lynx Binnenhof 5, 1200 Brussel, België	EU/1/00/132/001-050	28.3.2012
26.3.2012	VPRIV	Shire Pharmaceuticals Ireland Limited 5 Riverside Walk, Citywest Business Campus, Dublin 24, Ireland	EU/1/10/646/001-006	28.3.2012

— **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
15.3.2012	Livensa	Warner Chilcott Deutschland Gmbh Dr.-Otto-Röhm-Strasse 2-4, 64331 Weiterstadt, Deutschland	EU/1/06/351/001-003	19.3.2012

— **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
2.3.2012	Omnitrope	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/06/332/001-012	6.3.2012

— **Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council** [1]**): Accepted**

Date of the Décision	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
8.3.2012	Zulvac 1+8 Bovis	—	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/12/139/001-003	Suspension for injection	QI02AA08	12.3.2012

[1] OJ L 136, 30.4.2004, p. 1.

— **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
2.3.2012	Easotic	VIRBAC S.A 1ère Avenue 2065 m L.I.D. – 06516 Carros – France	EU/2/08/085/001-006	6.3.2012
2.3.2012	Flexicam	Dechra Veterinary Products A/S Mekuvej 9, 7171 Uldum, Danmark	EU/2/06/058/004	6.3.2012
9.3.2012	Purevax Rabies	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/10/117/001-003	13.3.2012
15.3.2012	BTVPUR AlSap 8	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/09/094/001-004	19.3.2012
15.3.2012	Masivet	AB Science S.A. 3 avenue George V, 75008 Paris, France	EU/2/08/087/001-003	19.3.2012
15.3.2012	Recuvyra	Nexcyon Pharmaceuticals Ltd. Bank Barn, How Mill, Brampton, Cumbria CA8 9JY, United Kingdom	EU/2/11/127/001	20.3.2012
26.3.2012	Aivlosin	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	EU/2/04/044/001-013	28.3.2012

— **Withdrawal of a marketing authorization (Article 38 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
19.3.2012	Gonazon	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/03/040/001-002	22.3.2012
19.3.2012	Zubrin	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/028/002-008	22.3.2012

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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