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 April 2012 to 30 April 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 148/01)

[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
13.4.2012	Bronchitol	Mannitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire, SL1 7LW, United Kingdom	EU/1/12/760/001-002	Inhalation powder, hard capsule	R05CB16	18.4.2012
13.4.2012	Sabervel	Irbesartan	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/12/765/001-006	Film-coated tablet	C09CA04	17.4.2012
20.4.2012	Capecitabine Accord	capecitabine	Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF United Kingdom	EU/1/12/762/001-018	Film-coated tablet	L01BC06	25.4.2012
20.4.2012	Capecitabine Krka	capecitabine	KRKA, d.d Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia	EU/1/12/763/001-018	Film-coated tablet	L01BC06	25.4.2012
20.4.2012	Capecitabine Teva	capecitabine	TEVA Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/12/761/001-002	Film-coated tablet	L01BC06	25.4.2012
20.4.2012	Nimenrix	Meningococcal group A, C, W-135 and Y conjugate vaccine	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/12/767/001-007	Powder and solvent for solution for injection	J07AH08	25.4.2012
20.4.2012	SANCUSO	granisetron	ProStrakan Limited Galabank Business Park, Galashiels, TD1 1QH, United Kingdom	EU/1/12/766/001	Transdermal patch	A04AA02	25.4.2012

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
20.4.2012	Zoledronic acid Actavis	zoledronic acid	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, Hafnarfjörður 220, Iceland	EU/1/12/759/001-003	Concentrate for solution for infusion	M05BA08	26.4.2012
24.4.2012	Signifor	pasireotide	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/12/753/001-012	Solution for injection	H01CB05	27.4.2012

— **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
3.4.2012	Kinzalkomb	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/02/214/001-015	5.4.2012
4.4.2012	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/03/256/001-010	10.4.2012
4.4.2012	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/069/001a-001b EU/1/98/069/002a-002b EU/1/98/069/003a-003b EU/1/98/069/004a-004b EU/1/98/069/005a-005b EU/1/98/069/006a-006b EU/1/98/069/007a-007b EU/1/98/069/008-010 EU/1/98/069/011a-011b EU/1/98/069/012	11.4.2012
4.4.2012	Rebetol	Schering Plough Europe Clos du Lynx 5, 1200 Bruxelles, Belgique – Lynx Binnenhof 5, 1200 Brussel, België	EU/1/99/107/001-005	11.4.2012
4.4.2012	Telzir	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/04/282/001-002	11.4.2012
10.4.2012	Vedrop	Orphan Europe SARL Immeuble Le Wilson - 70 Avenue du Général de Gaulle - F 92 800 Puteaux - France	EU/1/09/533/001-003	12.4.2012
13.4.2012	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/07/387/001-026	17.4.2012
13.4.2012	alli	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/401/007-016	17.4.2012
13.4.2012	Champix	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/360/001-013	17.4.2012

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
13.4.2012	Evoltra	Genzyme Europe BV Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/06/334/001-005	17.4.2012
13.4.2012	Foscan	Biolitec pharma Ltd United Drug House, Magna Drive, Dublin 24, Ireland	EU/1/01/197/003-005	17.4.2012
13.4.2012	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	17.4.2012
13.4.2012	Prometax	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/092/001-026	17.4.2012
13.4.2012	Revatio	Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/05/318/001	17.4.2012
13.4.2012	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex, UB11 1DB, United Kingdom	EU/1/07/391/001-004	17.4.2012
13.4.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	17.4.2012
13.4.2012	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/440/001-006	17.4.2012
13.4.2012	Viramune	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/97/055/001-009	17.4.2012
13.4.2012	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	17.4.2012
20.4.2012	Abraxane	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex, UB11 1DB, United Kingdom	EU/1/07/428/001	24.4.2012

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
20.4.2012	Aclasta	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/308/001-002	25.4.2012
20.4.2012	Aflunov	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/658/001-002	26.4.2012
20.4.2012	Altargo	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/390/001-004	26.4.2012
20.4.2012	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285/001-036	26.4.2012
20.4.2012	Ceplene	EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland	EU/1/08/477/001	24.4.2012
20.4.2012	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square, The Forbury, Reading, Berkshire RG1 3EB, United Kingdom	EU/1/07/392/001-003	25.4.2012
20.4.2012	Exelon	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/066/001-026	26.3.2012
20.4.2012	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/07/385/001-002 EU/1/07/385/004	26.4.2012
20.4.2012	HALAVEN	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/11/678/001-002	25.4.2012
20.4.2012	Helixate NexGen	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/144/001-005	25.4.2012
20.4.2012	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/03/256/002-010	25.4.2012

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
20.4.2012	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/06/368/001-015 EU/1/06/368/020-024 EU/1/06/368/029-033 EU/1/06/368/037-042 EU/1/06/368/047-051 EU/1/06/368/056-057 EU/1/06/368/088-102 EU/1/06/368/113-150 EU/1/06/368/163-168	25.4.2012
20.4.2012	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030/028-195	26.4.2012
20.4.2012	IOA	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/11/689/001-002	24.4.2012
20.4.2012	Iressa	AstraZeneca AB S 151 85 Sodertalje, Sverige	EU/1/09/526/001-002	26.4.2012
20.4.2012	Kogenate Bayer	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/143/004-013	25.4.2012
20.4.2012	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134/001-037	25.4.2012
20.4.2012	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	26.4.2012
20.4.2012	NovoNorm	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/98/076/004-006 EU/1/98/076/011-013 EU/1/98/076/018-020 EU/1/98/076/022-024	26.3.2012
20.4.2012	Opgenra	Olympus Biotech International Limited Raheen Business Park, Limerick, Ireland	EU/1/08/489/001-002	24.4.2012
20.4.2012	Optimark	Covidien Deutschland GmbH Gewerbepark 1, 93333 Neustadt/Donau, Deutschland	EU/1/07/398/001-014	26.3.2012
20.4.2012	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133/001-032	25.4.2012
20.4.2012	Pelzont	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/460/001-014	25.4.2012

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
20.4.2012	Prandin	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/00/162/003-005 EU/1/00/162/009-011 EU/1/00/162/015-017 EU/1/00/162/019-021	26.4.2012
20.4.2012	Preotact	Nycomed Danmark ApS Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/06/339/001-003	25.4.2012
20.4.2012	Prolia	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	24.4.2012
20.4.2012	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	26.4.2012
20.4.2012	Rasilamlo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/686/001-056	24.4.2012
20.4.2012	Rasilez	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	24.4.2012
20.4.2012	Riprazo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-040	24.4.2012
20.4.2012	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	24.4.2012
20.4.2012	Samsca	Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1LX, United Kingdom	EU/1/09/539/001-004	24.4.2012
20.4.2012	Sebivo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/388/001-003	26.4.2012
20.4.2012	Silodyx	Recordati Ireland Ltd. Raheens East, Ringaskiddy Co. Cork, Ireland	EU/1/09/607/001-014	24.4.2012

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
20.4.2012	Sprimeo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-040	24.4.2012
20.4.2012	Sprimeo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/683/001-080	24.4.2012
20.4.2012	Tracleer	Actelion Registration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220/001-006	26.4.2012
20.4.2012	Tredaptive	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/459/001-014	25.4.2012
20.4.2012	Trevaclyn	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/458/001-014	25.4.2012
20.4.2012	Urorec	Recordati Ireland Ltd. Raheens East, Ringaskiddy Co. Cork, Ireland	EU/1/09/608/001-014	24.4.2012
20.4.2012	Ventavis	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/255/001-008	26.4.2012
20.4.2012	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	25.4.2012
20.4.2012	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	24.4.2012
20.4.2012	Vidaza	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/08/488/001	24.4.2012
20.4.2012	Xenical	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/071/001-006	24.4.2012

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
20.4.2012	Yttriga	Eckert & Ziegler Radiopharma GmbH Robert-Rössle-Str. 10, 13125 Berlin, Deutschland	EU/1/05/322/001-002	26.4.2012
20.4.2012	Zoely	Theramex S.r.l. Via Messina 38, 20154 Milano, Italia	EU/1/11/690/001-002	24.4.2012
24.4.2012	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614/001-003	27.4.2012
24.4.2012	Rasilez HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	27.4.2012
24.4.2012	Temomedac	medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstrasse 3, D-20354 Hamburg - Deutschland	EU/1/09/605/001-012	27.4.2012
26.4.2012	Revolade	GlaxoSmithKline Trading Services Limited 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland	EU/1/10/612/001-006	30.4.2012
26.4.2012	Yervoy	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/698/001-002	30.4.2012

— **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
20.4.2012	PhotoBarr	Pinnacle Biologics B.V. p/a Trust Company Amsterdam B.V., Crystal Tower 21st Floor, Orlyplein 10, 1043 DP Amsterdam, Nederland	EU/1/04/272/001-002	25.4.2012
24.4.2012	Refludan	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/97/035/001-004	27.4.2012

— **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
10.4.2012	Slentrol	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/07/071/001-003	12.4.2012
13.4.2012	Cerenia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/06/062/005	17.4.2012
20.4.2012	BTVPUR AlSap 1	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/10/112/001-005	25.4.2012
20.4.2012	BTVPUR AlSap 1-8	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/10/113/001-005	25.4.2012
20.4.2012	Loxicom	Norbrook Laboratories Limited Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090/001-027	24.4.2012
20.4.2012	Meloxivet	Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse, België	EU/2/07/077/001-005	25.4.2012

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

The European Medicines Agency
7, Westferry Circus,
Canary Wharf
UK - LONDON E14 4H