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 February 2012 to 29 February 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 94/01)

[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
13.2.2012	Colobreathe	Colistimethate sodium	Forest Laboratories UK Ltd Riverbridge House, Anchor Boulevard, Crossways Business Park, Dartford, Kent DA2 6SL, United Kingdom	EU/1/11/747/001	Inhalation powder, hard capsule	R07AX	15.2.2012
17.2.2012	Caprelsa	vandetanib	AstraZeneca AB Building 411A, Floor 4, S-151 85 Sodertalje, Sverige	EU/1/11/749/001-002	Film-coated tablet	L01XE12	21.2.2012
17.2.2012	Vepacel	Prepandemic influenza vaccine (A/H5N1) (whole virion, Vero cell derived, inactivated)	Baxter Innovations GmbH Industriestrasse 67, A – 1221 Vienna, Österreich	EU/1/12/752/001	Suspension for injection	J07BB01	21.2.2012
17.2.2012	Zelboraf	vemurafenib	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/12/751/001	Film-coated tablet	L01XE15	21.2.2012
23.2.2012	Esmya	ulipristal	PregLem France SAS. 32, route de l'Eglise, 74140 Massongy, France	EU/1/12/750/001	Tablet	Pending	28.2.2012

— **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
9.2.2012	Sumatriptan Galpharm	Galpharm Healthcare Ltd. Dodworth Business ParkDodworth, Barnsley S75 3SP United Kingdom		13.2.2012

— **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
6.2.2012	Aclasta	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/308/001-002	9.2.2012
6.2.2012	Aflunov	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/658/001-002	9.2.2012
6.2.2012	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/02/224/001-005	8.2.2012
6.2.2012	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	9.2.2012
6.2.2012	Corlentor	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes, Cedex, France	EU/1/05/317/001-014	8.2.2012
6.2.2012	Dificlir	FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland	EU/1/11/733/001-004	9.2.2012
6.2.2012	Erbitux	Merck KGaA Frankfurter Straße 250, 64271 Darmstadt, Deutschland	EU/1/04/281/001-005	8.2.2012
6.2.2012	Intanza	Sanofi Pasteur MSD SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/08/505/001-006	8.12.2012
6.2.2012	Olanzapine Apotex	Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland	EU/1/10/635/001-018	8.2.2012

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
6.2.2012	Optimark	Covidien Deutschland GmbH Gewerbepark 1, 93333 Neustadt/Donau, Deutschland	EU/1/07/398/001-014	8.2.2012
6.2.2012	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389/001-003	8.2.2012
6.2.2012	Prialt	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts, AL10 9SN, United Kingdom	EU/1/04/302/001-004	8.2.2012
6.2.2012	Rapamune	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/01/171/001	9.2.2012
6.2.2012	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	8.2.2012
6.2.2012	Rilonacept Regeneron	Regeneron UK Limited 40 Bank Street, London E14 5DS, United Kingdom	EU/1/09/582/001	9.2.2012
6.2.2012	Simponi	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/09/546/001-004	8.2.2012
6.2.2012	Sonata	Meda AB Pipers väg 2A, 170 09 Solna, Sverige	EU/1/99/102/001-006	8.2.2012
6.2.2012	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/95/002/001-005	8.2.2012
6.2.2012	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/08/445/001-014	8.2.2012
6.2.2012	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/710/001-007	9.2.2012
6.2.2012	Yellox	Croma-Pharma GmbH Industriezeile 6, A-2100 Leobendorf, Österreich	EU/1/11/692/001	9.2.2012

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
9.2.2012	Aerius	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/160/001-013 EU/1/00/160/022-034 EU/1/00/160/036-069	13.2.2012
9.2.2012	Arzerra	Glaxo Group Ltd Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/625/001 EU/1/10/625/003	13.2.2012
9.2.2012	Azomyr	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/157/001-013 EU/1/00/157/022-067	13.2.2012
9.2.2012	Olazax Disperzi	Glenmark Pharmaceuticals s.r.o. City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika	EU/1/09/592/001-005	13.2.2012
9.2.2012	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	13.2.2012
9.2.2012	Prepandemic Influenza	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/657/001-002	13.2.2012
9.2.2012	Prepandemic Influenza	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/657/001-002	13.2.2012
9.2.2012	Procoralan	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/05/316/001-014	13.2.2012
9.2.2012	Rivastigmine HEXAL	HEXAL AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/09/589/001-018	13.2.2012
13.2.2012	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square, The Forbury, Reading, Berkshire RG1 3EB, United Kingdom	EU/1/07/392/001-003	15.2.2012
13.2.2012	Cystadane	Orphan Europe S.a.r.l. Immeuble Le Wilson, 70 Avenue du Général de Gaulle, 92800 Puteaux, France	EU/1/06/379/001	15.2.2012

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
17.2.2012	Aerinaze	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/399/001-006	21.2.2012
17.2.2012	Elonva	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/09/609/001-002	22.2.2012
17.2.2012	Fablyn	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/1/08/500/001-004	22.2.2012
17.2.2012	Faslodex	AstraZeneca UK Limited Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom	EU/1/03/269/001-002	22.2.2012
17.2.2012	Gliolan	medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstrasse 3, D-20354 Hamburg – Deutschland	EU/1/07/413/001-003	22.2.2012
17.2.2012	Herceptin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/145/001	21.2.2012
17.2.2012	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436/001-002	21.2.2012
17.2.2012	Myocet	Cephalon Europe 5 Rue Charles Martigny, 94700 Maisons Alfort, France	EU/1/00/141/001-002	22.2.2012
17.2.2012	Neoclarityn	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/161/001-013 EU/1/00/161/022-067	22.2.2012
17.2.2012	Olanzapine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/07/427/001-057	21.2.2012
17.2.2012	Olazax	Glenmark Pharmaceuticals s.r.o. City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika	EU/1/09/597/001-005	21.2.2012
17.2.2012	Replagal	Shire Human Genetic Therapies AB Svärdvägen 11D, 182 33 Danderyd, Sverige	EU/1/01/189/001-006	22.2.2012

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
17.2.2012	Rivastigmine 1 A Pharma	1 A Pharma GmbH Keltenring 1+3, 82041 Oberhaching, Deutschland	EU/1/09/585/001-018	22.2.2012
17.2.2012	Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/09/599/001-018	21.2.2012
17.2.2012	Tractocile	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, 2300 Copenhagen S, Danmark	EU/1/99/124/001-002	21.2.2012
17.2.2012	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423/001-003	22.2.2012
21.2.2012	Aloxi	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Republic of Ireland	EU/1/04/306/001-003	23.2.2012
21.2.2012	Angiox	The Medicines Company UK Ltd 115 L Milton Park, Abingdon, Oxfordshire, OX14 4SA, United Kingdom	EU/1/04/289/001	23.2.2012
21.2.2012	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268/001-004	24.2.2012
21.2.2012	Cubicin	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/328/001-004	24.2.2012
21.2.2012	Evra	Janssen-Cilag International NV Turnhoutseweg, 30 – 2340 Beerse – België	EU/1/02/223/001-003	24.2.2012
21.2.2012	Fertavid	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/510/001-019	24.2.2012
21.2.2012	Glivec	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/198/001-013	23.2.2012
21.2.2012	Kaletra	Abbott Laboratories Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berks, SL6 4XE United Kingdom	EU/1/01/172/001-008	23.2.2012

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
21.2.2012	Levitra	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/248/001-023	23.2.2012
21.2.2012	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292/001-012	23.2.2012
21.2.2012	PREZISTA	Janssen-Cilag International NV Turnhoutseweg, 30 – 2340 Beerse – België	EU/1/06/380/001-005	23.2.2012
21.2.2012	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	24.2.2012
21.2.2012	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	23.2.2012
21.2.2012	RotaTeq	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/348/001-002	24.2.2012
21.2.2012	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/363/001-015	23.2.2012
21.2.2012	Stelara	Janssen-Cilag International NV Turnhoutseweg, 30 – 2340 Beerse – België	EU/1/08/494/001-004	24.2.2012
21.2.2012	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	23.2.2012
21.2.2012	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	24.2.2012
21.2.2012	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef, 60, 1070 Brussel, België	EU/1/08/470/001-019	23.2.2012
21.2.2012	Visudyne	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/00/140/001	23.2.2012

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
21.2.2012	Vivanza	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/249/001-015	24.2.2012
21.2.2012	Zostavax	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/341/001-013	24.2.2012
23.2.2012	Clopidogrel Qualimed	Qualimed 117, Allée des Parcs, 69 800 Saint Priest, France	EU/1/09/557/001-010	27.2.2012
23.2.2012	Januvia	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383/001-018	27.2.2012
23.2.2012	Resolor	Shire-Movetis NV Veedjik 58, B-2300 Turnhout, België	EU/1/09/581/001-008	27.2.2012
27.2.2012	Bridion	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/08/466/001-002	29.2.2012
27.2.2012	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vinci Laan 15, B-1831 Diegem, België	EU/1/08/473/001-003	29.2.2012
27.2.2012	Instanyl	Nycomed Danmark ApS Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/09/531/001-021	29.2.2012
27.2.2012	Irbesartan HCT Zentiva (Ex-Winthrop)	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/06/377/001-028	1.3.2012
27.2.2012	Olanzapine Glenmark	Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom	EU/1/09/587/001-017	29.2.2012
27.2.2012	Olanzapine Glenmark Europe	Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom	EU/1/09/588/001-012	29.2.2012
27.2.2012	Prolia	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	29.2.2012

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
27.2.2012	Twynsta	Boehringer Ingelheim International GmbH Binger Strasse 173 – D - 55216 Ingelheim am Rhein, Deutschland	EU/1/10/648/001-028	29.2.2012

— **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
9.2.2012	Clopidogrel Acino Pharma	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/549/001-007	13.2.2012
9.2.2012	Clopidogrel Hexal	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/534/001-007	13.2.2012
13.2.2012	Clopidogrel Acino Pharma GmbH	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/548/001-007	15.2.2012

— **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
23.2.2012	RevitaCAM	Meloxicam	Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, UNITED KINGDOM	EU/2/12/138/001-003	Oromucosal spray	QM01AC06	27.2.2012

[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
17.2.2012	Purevax Rabies	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/10/117/001-003	21.2.2012
21.2.2012	Dicural	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/97/003/001-018	24.2.2012
27.2.2012	Reconcile	Eli Lilly and Company Ltd Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/08/080/001-004	29.2.2012

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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