IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2012 to 30 June 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 224/01)

[1] OJ L 136, 30.4.04, 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
15.06.2012	Rienso	Ferumoxytol	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/12/774/001-002	Solution for injection	Pending	20.06.2012

— **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
21.06.2012	Folotyn	Allos Therapeutics Limited 71 Knowl Piece, Wilbury Way, Hitchin, Hertfordshire SG4 0TY, United Kingdom	—	25.06.2012

— **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
01.06.2012	Osigraft	Olympus Biotech International Limited Raheen Business Park, Limerick, Ireland	EU/1/01/179/001	05.06.2012
11.06.2012	Levetiracetam Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/701/001-032	13.06.2012
11.06.2012	Mycophenolate mofetil Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/07/439/001-006	13.06.2012
11.06.2012	Myfenax	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/07/438/001-006	13.06.2012
14.06.2012	Nivestim	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/631/001-009	18.06.2012
14.06.2012	Quadramet	CIS bio international Boite Postale 32 - F-91192 Gif-sur-Yvette - France	EU/1/97/057/001	18.06.2012
15.06.2012	Abseamed	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37, D-58638 Iserlohn, Deutschland	EU/1/07/412/001-052	19.06.2012
15.06.2012	Azopt	Alcon Laboratories (UK) Ltd. Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/00/129/001-003	20.06.2012

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
15.06.2012	Epivir	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/96/015/002	20.06.2012
15.06.2012	Evra	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/02/223/001-003	19.06.2012
15.06.2012	Optimark	Covidien Deutschland GmbH Gewerbepark 1, Neustadt/Donau 93333, Deutschland	EU/1/07/398/001-014	19.06.2012
15.06.2012	Prevenar	Wyeth-Lederle Vaccines S.A. Pleainlaan 17 Boulevard de la Plaine, 1050 Brussels - Bruxelles, Belgium	EU/1/00/167/001-008	20.06.2012
15.06.2012	Temozolomide HEXAL	HEXAL AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/10/616/001-036	20.06.2012
15.06.2012	Temozolomide Sandoz	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/10/617/001-002 EU/1/10/617/005-006 EU/1/10/617/009-010 EU/1/10/617/013-014 EU/1/10/617/017-018 EU/1/10/617/021-022 EU/1/10/617/025-036	20.06.2012
18.06.2012	Atriance	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/403/001	21.06.2012
18.06.2012	Binocrit	Sandoz GmbH Biochemiestrasse 10, Kundl 6250, Österreich	EU/1/07/410/001-052	21.06.2012
18.06.2012	Epoetin alfa Hexal	Hexal AG. Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/07/411/001-052	21.06.2012
18.06.2012	GILENYA	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/677/001-005	20.06.2012

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
18.06.2012	GILENYA	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/677/001-005	22.06.2012
18.06.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	20.06.2012
18.06.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	20.06.2012
21.06.2012	alli	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/401/007-016	25.06.2012
21.06.2012	Cimzia	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/09/544/001-002	20.06.2012
21.06.2012	Ketek	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92160 Antony, France	EU/1/01/191/001-005	25.06.2012
21.06.2012	Tarceva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/05/311/001-003	25.06.2012
21.06.2012	Yervoy	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/698/001-002	25.06.2012
27.06.2012	Abraxane	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex, UB11 1DB, United Kingdom	EU/1/07/428/001	02.07.2012

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
27.06.2012	Actraphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/229/001-004 EU/1/02/229/036-037	29.06.2012
27.06.2012	Actrapid	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/230/001-004 EU/1/02/230/016-017	29.06.2012
27.06.2012	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	02.07.2012
27.06.2012	Cimzia	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/09/544/001-002	29.06.2012
27.06.2012	Dificlir	Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland	EU/1/11/733/001-004	29.06.2012
27.06.2012	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/03/256/001-010	02.07.2012
27.06.2012	Insulatard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/233/003-004 EU/1/02/233/017	02.07.2012
27.06.2012	Invanz	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/02/216/001-002	29.06.2012
27.06.2012	Invega	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/07/395/001-095	02.07.2012

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
27.06.2012	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026/001-002	29.06.2012
27.06.2012	Irbesartan HCT Zentiva (Ex-Winthrop)	Sanofi 54, rue La Boétie, 75008 Paris, France	EU/1/06/377/001-034	03.07.2012
27.06.2012	Javlor	Pierre Fabre Médicament 45, place Abel Gance, F-92100 Boulogne, France	EU/1/09/550/001-012	02.07.2012
27.06.2012	Karvezide	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/98/085/001-034	29.06.2012
27.06.2012	Lucentis	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/374/001	29.06.2012
27.06.2012	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614/001-003	29.06.2012
27.06.2012	Mixtard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/231/001-004 EU/1/02/231/036-037	02.07.2012
27.06.2012	Nexavar	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/06/342/001	02.07.2012
27.06.2012	Osseor	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/287/001-006	02.07.2012

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
27.06.2012	PREZISTA	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/06/380/001-005	02.07.2012
27.06.2012	Protaphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/234/003-004 EU/1/02/234/017	02.07.2012
27.06.2012	Protelos	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/288/001-006	02.07.2012
27.06.2012	Rebif	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/98/063/001-019	29.06.2012
27.06.2012	Revolade	GlaxoSmithKline Trading Services Limited 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland	EU/1/10/612/001-006	02.07.2012
27.06.2012	Stocrin	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111/001-005 EU/1/99/111/008 EU/1/99/111/010-011	02.07.2012
27.06.2012	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110/001-005 EU/1/99/110/008-010	02.07.2012
27.06.2012	Sycrest	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640/001-006	02.07.2012
27.06.2012	Synagis	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/99/117/001-002	29.06.2012

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
27.06.2012	Tasigna	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/422/001-012	02.07.2012
27.06.2012	Temodal	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, United Kingdom	EU/1/98/096/001-025	02.07.2012
27.06.2012	Trisenox	Cephalon Europe 5 Rue Charles Martigny, 94700 Maisons Alfort, Cedex, France	EU/1/02/204/001	02.07.2012
27.06.2012	Viracept	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/97/054/001 EU/1/97/054/004-005	29.06.2012
27.06.2012	VPRIV	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/10/646/001-006	02.07.2012
27.06.2012	Xeplion	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/672/001-006	02.07.2012
27.06.2012	Zeffix	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/99/114/003	02.07.2012
27.06.2012	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/479/001-003	29.06.2012

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
27.06.2012	Zyprexa	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/96/022/002 EU/1/96/022/004 EU/1/96/022/006 EU/1/96/022/009-012 EU/1/96/022/014 EU/1/96/022/016-017 EU/1/96/022/019-040	29.06.2012
27.06.2012	Zyprexa Velotab	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/99/125/001-020	29.06.2012
28.06.2012	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 54, rue La Boétie, 75008 Paris, France	EU/1/98/086/001-034	03.07.2012
28.06.2012	Copalia HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/575/001-060	03.07.2012
28.06.2012	Dafiro HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/574/001-060	03.07.2012
28.06.2012	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416/001-002	03.07.2012
28.06.2012	ellaOne	Laboratoire HRA Pharma 15, rue Béranger, 75003 Paris, France	EU/1/09/522/001	03.07.2012
28.06.2012	Exforge	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/370/001-039	03.07.2012

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
28.06.2012	Firmagon	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, Copenhagen S 2300, Danmark	EU/1/08/504/001-003	07.07.2012
28.06.2012	GONAL-f	Merck Serono Europe Ltd. 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/95/001/001 EU/1/95/001/003-005 EU/1/95/001/009 EU/1/95/001/012 EU/1/95/001/021-022 EU/1/95/001/025-028 EU/1/95/001/031-035	03.07.2012
28.06.2012	Icandra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/484/001-018	03.07.2012
28.06.2012	Imprida	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/373/001-039	03.07.2012
28.06.2012	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/1/06/368/163-174	04.07.2012
28.06.2012	Jalra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485/001-011	03.07.2012
28.06.2012	Lamivudine Teva Pharma B.V.	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/596/001-014	03.07.2012
28.06.2012	Myclausen	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, 14167 Berlin, Deutschland	EU/1/10/647/001-004	03.07.2012

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
28.06.2012	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	03.07.2012
28.06.2012	PritorPlus	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/02/215/001-021	04.07.2012
28.06.2012	Rasilez HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	03.07.2012
28.06.2012	Rilonacept Regeneron	Regeneron UK Limited 40 Bank Street, E14 5DS London, United Kingdom	EU/1/09/582/001	04.07.2012
28.06.2012	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	03.07.2012
28.06.2012	Siklos	ADDMEDICA 101, rue Saint Lazare, Paris 75009, France	EU/1/07/397/001-004	03.07.2012
28.06.2012	Siklos	ADDMEDICA 101, rue Saint Lazare, Paris 75009, France	EU/1/07/397/001-004	03.07.2012
28.06.2012	Sprimeo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/683/001-080	02.07.2012
28.06.2012	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	03.07.2012
28.06.2012	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/710/001-007	04.07.2012

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
28.06.2012	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/710/001-007	04.07.2012
28.06.2012	Vyndaqel	Pfizer Specialty UK Limited Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/11/717/001	04.07.2012
28.06.2012	Xiliarx	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/08/486/001-011	03.07.2012
28.06.2012	Zomarist	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/08/483/001-018	03.07.2012

— **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
28.06.2012	Hexavac	Aventis Pasteur MSD 8, rue Jonas Salk, 69007 Lyon, France	EU/1/00/147/001-012	04.07.2012

— 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
14.06.2012	Porcilis ColiClos	—	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/12/141/001-009	Suspension for injection	QI09AB08	17.06.2012
15.06.2012	Poulvac E. coli	—	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/2/12/140/001-008	Lyophilisate for suspension for spray vaccination	QI01AE04	20.06.2012

[1] OJ L 136, 30.4.04, 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
11.06.2012	Activyl	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/10/118/001-021	13.06.2012
14.06.2012	Emdocam	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/11/128/001-003	18.06.2012
27.06.2012	Bovilis BTV8	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/10/106/001-014	02.07.2012
28.06.2012	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/98/006/001-010	04.07.2012
28.06.2012	Oxyglobin	OPK Biotech Netherlands BV Teleportboulevard 140, 1043EJ Amsterdam, Nederland	EU/2/99/015/001-002	04.07.2012

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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