Summary of Community decisions on marketing authorisations in respect of medicinal products from 1 August 2009 to 31 August 2009

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

(2009/C 231/05)

— Issuing of a marketing authorisation (Article 13 of Regulation (EC) No 726/2004): Accepted

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
3.8.2009	Afinitor	Everolimus	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/538/001-006	Tablet	L01XE10	5.8.2009
3.8.2009	Samsca	Tolvaptan	Otsuka Pharmaceutical Europe Ltd Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU UNITED KINGDOM	EU/1/09/539/001-004	Tablet	C03XA01	5.8.2009

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

— **Modification of a marketing authorisation (Article 13 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
3.8.2009	SUTENT	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/06/347/001-008	5.8.2009
3.8.2009	Baraclude	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/343/001-007	5.8.2009
3.8.2009	INTELENCE	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	5.8.2009
3.8.2009	Revatio	Pfizer Limited Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/05/318/001	5.8.2009
3.8.2009	PegIntron	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/00/131/001-050	5.8.2009
3.8.2009	Champix	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/06/360/001-012	5.8.2009
3.8.2009	FOSAVANCE	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/05/310/001-009	5.8.2009
6.8.2009	Lucentis	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/374/001	10.8.2009
6.8.2009	TESAVEL	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/435/001-018	10.8.2009

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6.8.2009	Trevaclyn	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/08/458/001-014	10.8.2009
6.8.2009	Tasigna	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/07/422/001-004	10.8.2009
6.8.2009	Pelzont	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/08/460/001-014	10.8.2009
6.8.2009	Tredaptive	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/08/459/001-014	10.8.2009
7.8.2009	CELSENTRI	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/07/418/001-010	11.8.2009
7.8.2009	Prepandrix	GlaxoSmithKline Biologicals s.a. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/453/002	11.8.2009
7.8.2009	Lyrica	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/04/279/001-043	11.8.2009
7.8.2009	Revlimid	Celgene Europe Limited Riverside House Riverside Walk Windsor Berkshire SL4 1NA UNITED KINGDOM	EU/1/07/391/001-004	11.8.2009
13.8.2009	Oprymea	KRKA, d. d. Novo mesto Šmarješka cesta 6 SI-8501 Novo mesto SLOVENIJA	EU/1/08/469/001-025	17.8.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
13.8.2008	Clopidogrel BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/08/464/001-019	17.8.2009
13.8.2008	Clopidogrel Winthrop	Sanofi Pharma Bristol-Myers Squibb SNC 174 Avenue de France 75013 Paris FRANCE	EU/1/08/465/001-019	17.8.2009
18.8.2009	Nobilis Influenza H5N6	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/07/076/001-004	20.8.2009
20.8.2009	Lyrica	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/04/279/001-043	24.8.2009
20.8.2009	SUTENT	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/06/347/001-008	24.8.2009
20.8.2009	TESAVEL	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/435/001-018	24.8.2009
20.8.2009	Pramipexole Teva	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/08/490/001-016	24.8.2009
20.8.2009	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/08/442/001-008	24.8.2009
20.8.2009	Apidra	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/04/285/001-036	24.8.2009
21.8.2009	PEGASYS	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/02/221/001-010	25.8.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
21.8.2009	Galvus	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/07/414/001-010 EU/1/07/414/018	25.8.2009
21.8.2009	TORISEL	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/07/424/001	25.8.2009
21.8.2009	Jalra	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/08/485/001-011	25.8.2009
21.8.2009	Mycophenolate mofetil Teva	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/07/439/001-004	25.8.2009
21.8.2009	TARGRETIN	Eisai Limited, European Knowledge Centre Mosquito Way Hatfield Hertfordshire AL10 9SN UNITED KINGDOM	EU/1/01/178/001	25.8.2009
21.8.2009	AVANDIA	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS UNITED KINGDOM	EU/1/00/137/002-018	25.8.2009
21.8.2009	Myfenax	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/07/438/001-004	25.8.2009
21.8.2009	Kaletra	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/01/172/001-006	25.8.2009
21.8.2009	Myozyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND	EU/1/06/333/001-003	25.8.2009
21.8.2009	Luminity	Lantheus MI UK Limited One South Place London EC2M 2WG UNITED KINGDOM	EU/1/06/361/001-002	25.8.2009

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21.8.2009	Januvia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/383/001-018	25.8.2009
21.8.2009	Rotarix	GlaxoSmithKline Biologicals s.a. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/05/330/001-011	25.8.2009
21.8.2009	Privigen	CSL Behring GmbH Emil von Behring Strasse 76 35041 Marburg DEUTSCHLAND	EU/1/08/446/001-006	25.8.2009
21.8.2009	Competact	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych London WC2B 4AE UNITED KINGDOM	EU/1/06/354/001-009	25.8.2009
21.8.2009	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	25.8.2009
21.8.2009	Mabthera	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/98/067/001-002	25.8.2009
25.8.2009	Epoetin alfa Hexal	Hexal AG. Industriestrasse 25 83607 Holzkirchen DEUTSCHLAND	EU/1/07/411/001-020	27.8.2009
25.8.2009	Avandamet	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS UNITED KINGDOM	EU/1/03/258/001-022	27.8.2009
25.8.2009	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare 1611 Luxembourg LUXEMBOURG	EU/1/08/462/001-012	27.8.2009
25.8.2009	Tasigna	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/07/422/001-004	27.8.2009

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25.8.2009	Binocrit	Sandoz GmbH Biochemiestrasse 10 6250 Kundl ÖSTERREICH	EU/1/07/410/001-020	27.8.2009
25.8.2009	Xiliarx	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/08/486/001-011	27.8.2009
27.8.2009	Thalidomide Celgene	Celgene Europe Limited Riverside House Riverside Walk Windsor SL4 1NA UNITED KINGDOM	EU/1/08/443/001	1.9.2009
27.8.2009	CELVAPAN	Baxter AG Industriestraße 67 1221 Wien ÖSTERREICH	EU/1/08/506/001	1.9.2009
27.8.2009	Champix	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/06/360/001-012	1.9.2009
27.8.2009	Zeffix	Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/99/114/001-003	1.9.2009
27.8.2009	Iscover	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/98/070/001a-001b EU/1/98/070/002a-002b EU/1/98/070/003a-003b EU/1/98/070/004a-004b EU/1/98/070/005a-005b EU/1/98/070/006a-006b EU/1/98/070/007a-007b EU/1/98/070/008-010 EU/1/98/070/011a-011b	1.9.2009
27.8.2009	Xeristar	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/04/297/001-008	31.8.2009
27.8.2009	Vfend	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/02/212/001-026	1.9.2009

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28.8.2009	Pelzont	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/08/460/001-014	1.9.2009
28.8.2009	Tredaptive	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/08/459/001-014	1.9.2009
28.8.2009	Trevaclyn	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/08/458/001-014	1.9.2009
28.8.2009	Irbesartan Krka	KRKA, d.d. Novo mesto Šmarješka cesta 6 SI-8501 Novo mesto SLOVENIJA	EU/1/08/480/001-018	1.9.2009
28.8.2009	Volibris	Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/08/451/001-004	1.9.2009
28.8.2009	Panretin	Eisai Limited, European Knowledge Centre Mosquito Way Hatfield Hertfordshire AL10 9SN UNITED KINGDOM	EU/1/00/149/001	1.9.2009
28.8.2009	Humira	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/03/256/001-010	1.9.2009
28.8.2009	Forsteo	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/03/247/001-002	1.9.2009
28.8.2009	Invanz	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/02/216/001-002	1.9.2009
28.8.2009	Zerit	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/96/009/001-009	1.9.2009

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28.8.2009	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	1.9.2009
28.8.2009	Abseamed	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 58638 Iserlohn DEUTSCHLAND	EU/1/07/412/001-020	1.9.2009
28.8.2009	MicardisPlus	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/02/213/001-023	1.9.2009
28.8.2009	Eucreas	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/07/425/001-018	1.9.2009
28.8.2009	Aldara	Meda AB Pipers väg 2 SE-170 73 Solna SVËRIGE	EU/1/98/080/001	1.9.2009
28.8.2009	Xelevia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/382/001-018	1.9.2009
31.8.2009	Betaferon	Bayer Schering Pharma AG Müllerstrasse 170-178 13342 Berlin DEUTSCHLAND	EU/1/95/003/009-010	2.9.2009
31.8.2009	Neupro	Schwarz Pharma Ltd Shannon, Industrial Estate Co.Clare IRELAND	EU/1/05/331/001-055	2.9.2009
31.8.2009	Icandra	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/08/484/001-018	2.9.2009
31.8.2009	Mimpara	Amgen Europe B.V. Minervum 7061 4817 ZK Breda NEDERLAND	EU/1/04/292/001-012	2.9.2009

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31.8.2009	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd. 61 Aldwich London WC2B 4AE UNITED KINGDOM	EU/1/06/366/005-022	2.9.2009
31.8.2009	Gardasil	Sanofi Pasteur MSD, SNC 8 rue Jonas Salk 69007 Lyon FRANCE	EU/1/06/357/001-021	2.9.2009
31.8.2009	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited Unit 13, Stillorgan Industrial Park Blackrock, Co.Dublin IRELAND	EU/1/07/430/001-002	2.9.2009

— **Modification of a marketing authorisation (Article 38 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
27.8.2009	Aivlosin	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS UNITED KINGDOM	EU/2/04/044/001-010	31.8.2009
31.8.2009	Locatim	Biokema Anstalt Pflugstrasse 12 9490 Vaduz, Fürstentum LIECHTENSTEIN	EU/2/99/011/001	2.9.2009

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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