

**Summary of Community decisions on marketing authorizations in respect of medicinal products
from 1 March 2009 to 31 March 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 101/03)

— Issuing of a marketing authorization (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 authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
4.3.2009	CELVAPAN	Pandemic influenza vaccine (H5N1 whole virion, Vero cell derived, inactivated)	Baxter AG Industriestraße 67 A - 1221 Wien ÖSTERREICH	EU/1/08/506/001	Suspension for injection	J07BB01	6.3.2009
6.3.2009	MEPACT	mifamurtide	IDM Pharma S.A. 47 rue de Chaillot 75116 Paris FRANCE	EU/1/08/502/001	Powder for suspension for infusion	L03AX15	23.3.2009
19.3.2009	Fertavid	follitropin beta	SP Europe Rue de Stalle 73 B-1180 Bruxelles BELGIQUE	EU/1/09/510/001-019	Solution for injection	G03G A06	23.3.2009
30.3.2009	Synflorix	Pneumococcal polysaccharide conjugate vaccine (adsorbed)	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/09/508/001-009	Suspension for injection	J07AL52	31.3.2009
31.3.2009	Ribavirin Teva	Ribavirin	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/509/001-004	Capsule, hard	J05A B04	2.4.2009
31.3.2009	IXIARO	Japanese Encephalitis vaccine (inactivated, adsorbed)	Intercell AG Campus Vienna Biocenter 3 A-1030 Wien ÖSTERREICH	EU/1/08/501/001-002	Suspension for injection	J07BA02	2.4.2009

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004): 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
2.3.2009	Fendrix	GlaxoSmithKline Biologicals s.a. rue de l'Institut 89 Rixensart, B-1330 BELGIQUE	EU/1/04/299/001-003	4.3.2009
2.3.2009	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/04/296/001-009	4.3.2009
2.3.2009	Fareston	Orion Corporation Orionintie 1 FIN-02200 Espoo SUOMI	EU/1/96/004/001-002	4.3.2009
2.3.2009	Nexavar	Bayer HealthCare AG D-51368 Leverkusen DEUTSCHLAND	EU/1/06/342/001	4.3.2009
2.3.2009	Irbesartan BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/375/001-033	4.3.2009
2.3.2009	Aptivus	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/05/315/001	4.3.2009
2.3.2009	Ganfort	Allergan Pharmaceuticals Ireland Castlebar Road Westport, Co. Mayo IRELAND	EU/1/06/340/001-002	5.3.2009
4.3.2009	KOGENATE Bayer	Bayer HealthCare AG 51368 Leverkusen DEUTSCHLAND	EU/1/00/143/001-011	6.3.2009
4.3.2009	Helixate NexGen	Bayer HealthCare AG 51368 Leverkusen DEUTSCHLAND	EU/1/00/144/001-004	6.3.2009
4.3.2009	Gardasil	Sanofi Pasteur MSD SNC, 8, rue Jonas Salk 69007 Lyon FRANCE	EU/1/06/357/001-021	6.3.2009
4.3.2009	Cystadane	Orphan Europe S.a.r.l. Immeuble Le Wilson 70 Avenue du Général de Gaulle 92800 Puteaux FRANCE	EU/1/06/379/001	6.3.2009

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4.3.2009	Photobarr	Axcan Pharma International BV Engelenkampstraat 72 6131 JJ Sittard NEDERLAND	EU/1/04/272/001-002	6.3.2009
6.3.2009	Silgard	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/06/358/001-021	10.3.2009
6.3.2009	BYETTA	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/06/362/001-004	10.3.2009
6.3.2009	IntronA	Schering Plough Europe Rue de Stalle, 73 1180 Bruxelles BELGIQUE	EU/1/99/127/001-044	10.3.2009
6.3.2009	Remicade	Centocor B.V. Einsteinweg 101 2333 CB Leiden NEDERLAND	EU/1/99/116/001-005	10.3.2009
6.3.2009	Protelos	Les Laboratoires Servier 22, rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/04/288/001-006	10.3.2009
6.3.2009	ATryn	LEO Pharma A/S Industriparken 55 DK-2750 Ballerup DANMARK	EU/1/06/355/001-003	10.3.2009
6.3.2009	Irbesartan Hydrochloro- thiazide Winthrop	SANOFI PHARMA BRISTOL MYERS SQUIBB SNC 174 avenue de France F- 75013 Paris FRANCE	EU/1/06/377/001-028	10.3.2009
9.3.2009	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main DEUTSCHLAND	EU/1/00/133/001-032	11.3.2009
9.3.2009	Osseor	Les Laboratoires Servier 22, rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/04/287/001-006	11.3.2009
9.3.2009	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/99/110/001-009	11.3.2009

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10.3.2009	DULOXETINE BOEHRINGER INGELHEIM	Boehringer Ingelheim International GmbH Binger Strasse 173 - D - 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/08/471/001-012	12.3.2009
17.3.2009	Pritor Plus	Bayer HealthCare AG 51368 Leverkusen DEUTSCHLAND	EU/1/02/215/001-021	19.3.2009
17.3.2009	Irbesartan Winthrop	SANOFI PHARMA BRISTOL MYERS SQUIBB SNC 174 avenue de France F- 75013 Paris FRANCE	EU/1/06/376/001-033	19.3.2009
17.3.2009	Pritor	Bayer HealthCare AG 51368 Leverkusen DEUTSCHLAND	EU/1/98/089/001-022	19.3.2009
17.3.2009	Hycamtin	SmithKline Beecham plc 980 Great West Road, Brentford Middlesex, TW8 9GS UNITED KINGDOM	EU/1/96/027/001 EU/1/96/027/003-007	19.3.2009
17.3.2009	Onsenal	Pfizer Limited Ramsgate Road, Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/03/259/001-006	19.3.2009
18.3.2009	Irbesartan HCT BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/369/001-028	20.3.2009
18.3.2009	Atriance	Glaxo Group Limited Berkeley Avenue, Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/403/001	20.3.2009
18.3.2009	Kinzalkomb	Bayer HealthCare AG 51368 Leverkusen DEUTSCHLAND	EU/1/02/214/001-015	20.3.2009
18.3.2009	MicardisPlus	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/02/213/001-023	20.3.2009
18.3.2009	Kinzalmono	Bayer HealthCare AG 51368 Leverkusen DEUTSCHLAND	EU/1/98/091/001-014	20.3.2009
19.3.2009	Regranex	Janssen-Cilag International NV Turnhoutseweg 30 - 2340 Beerse - BELGIË	EU/1/99/101/001	23.3.2009

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19.3.2009	Stalevo	Orion Corporation Orionintie 1 FIN-02200 Espoo SUOMI	EU/1/03/260/001-023	23.3.2009
19.3.2009	Micardis	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/98/090/001-020	23.3.2009
19.3.2009	Vectibix	Amgen Europe B.V. Minervum 7061 NL-4817 ZK Breda NEDERLAND	EU/1/07/423/001-003	23.3.2009
23.3.2009	NovoSeven	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd DANMARK	EU/1/96/006/001-003	25.3.2009
23.3.2009	Irbesartan BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/375/001-033	25.3.2009
25.3.2009	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park Welwyn Garden City, AL7 1TW UNITED KINGDOM	EU/1/04/300/001-002	27.3.2009
25.3.2009	Enbrel	Wyeth Europa Limited Huntercombe Lane South, Taplow Maidenhead, Berkshire, SL6 0PH UNITED KINGDOM	EU/1/99/126/001-018	27.3.2009
25.3.2009	Telzir	Glaxo Group Ltd. Greenford Road, Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/04/282/001-002	27.3.2009
25.3.2009	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/04/283/001-012	27.3.2009
25.3.2009	Exjade	Novartis Europharm Limited Wimblehurst Road, Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/356/001-009	27.3.2009
25.3.2009	Arixtra	Glaxo Group Ltd. Greenford Road, Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/02/206/001-035	27.3.2009

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25.3.2009	Xenical	Roche Registration Limited 6 Falcon Way, Shire Park Welwyn Garden City, AL7 1TW UNITED KINGDOM	EU/1/98/071/001-006	27.3.2009
25.3.2009	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/04/296/001-009	27.3.2009
25.3.2009	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19 NL-2353 EW Leiderdorp NEDERLAND	EU/1/07/387/001-010	27.3.2009
25.3.2009	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/08/442/001-008	27.3.2009
25.3.2009	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/1/96/022/008-012 EU/1/96/022/014 EU/1/96/022/016-017 EU/1/96/022/019-034	27.3.2009
25.3.2009	ProQuad	Sanofi Pasteur MSD SNC, 8, rue Jonas Salk 69007 Lyon FRANCE	EU/1/05/323/001-013	27.3.2009
25.3.2009	Cetrotide	Serono Europe Limited 56, Marsh Wall London E14 9TP UNITED KINGDOM	EU/1/99/100/001-003	27.3.2009
25.3.2009	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/440/001-002	27.3.2009
25.3.2009	Lysodren	Laboratoire HRA Pharma 15, rue Béranger 75003 Paris FRANCE	EU/1/04/273/001	27.3.2009
25.3.2009	Zyprexa Velotab	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/99/125/001-016	27.3.2009
25.3.2009	Yondelis	Pharma Mar, S.A. Avda. de los Reyes 1 Polígono Industrial La Mina 28770 Colmenar Viejo (Madrid) ESPAÑA	EU/1/07/417/001-002	27.3.2009

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
25.3.2009	Extavia	Novartis Europharm Limited Wimblehurst Road, Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/08/454/001-002 EU/1/08/454/005	27.3.2009
25.3.2009	Mabthera	Roche Registration Limited 6 Falcon Way, Shire Park Welwyn Garden City, AL7 1TW UNITED KINGDOM	EU/1/98/067/001-002	27.3.2009
25.3.2009	Beromun	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/99/097/001	27.3.2009
25.3.2009	Dukoral	SBL Vaccin AB S-105 21 Stockholm SWEDEN	EU/1/03/263/001-003	30.3.2009
25.3.2009	NeuroBloc	Eisai Limited 3, Shortlands London W6 8EE UNITED KINGDOM	EU/1/00/166/001-003	30.3.2009
25.3.2009	Xeristar	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/04/297/001-008	27.3.2009
27.3.2009	Aerinaze	SP Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel BELGIË	EU/1/07/399/001-006	1.4.2009
27.3.2009	Liprolog	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/01/195/001-015 EU/1/01/195/022-025	1.4.2009
27.3.2009	Karvezide	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/98/085/001-034	1.4.2009
27.3.2009	Irbesartan HCT Winthrop	SANOFI PHARMA BRISTOL MYERS SQUIBB SNC 174 avenue de France F- 75013 Paris FRANCE	EU/1/06/377/001-028	1.4.2009
27.3.2009	Litak	Lipomed GmbH Schönaugasse 11 D-79713 Bad Säckingen DEUTSCHLAND	EU/1/04/275/001-002	1.4.2009

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27.3.2009	Procoralan	Les Laboratoires Servier 22, rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/05/316/001-014	1.4.2009
27.3.2009	Mimpara	Amgen Europe B.V. Minervum 7061 NL-4817 ZK Breda NEDERLAND	EU/1/04/292/001-012	1.4.2009
27.3.2009	TRIZIVIR	Glaxo Group Ltd. Greenford Road, Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/00/156/002-003	1.4.2009
27.3.2009	Dafiro	Novartis Europharm Limited Wimblehurst Road, Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/371/001-036	1.4.2009
27.3.2009	Copalia	Novartis Europharm Limited Wimblehurst Road, Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/372/001-036	1.4.2009
27.3.2009	Imprida	Novartis Europharm Limited Wimblehurst Road, Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/373/001-036	1.4.2009
27.3.2009	Exforge	Novartis Europharm Limited Wimblehurst Road, Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/370/001-036	1.4.2009
27.3.2009	Stalevo	Orion Corporation Orionintie 1 FIN-02200 Espoo SUOMI	EU/1/03/260/024-033	1.4.2009
30.3.2009	Cholestagel	Genzyme Europe B.V. Gooimeer 10 NL-1411 DD Naarden NEDERLAND	EU/1/03/268/001-004	1.4.2009
31.3.2009	Rapilysin	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður ICELAND	EU/1/96/018/001	2.4.2009
31.3.2009	Velcade	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse BELGIË	EU/1/04/274/001-002	2.4.2009

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
31.3.2009	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris FRANCE	EU/1/97/046/001-039	2.4.2009
31.3.2009	Karvea	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/97/049/001-039	2.4.2009
31.3.2009	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris FRANCE	EU/1/98/086/001-034	2.4.2009

— **Withdrawal of a marketing authorization (Article 13 of Regulation (EC) No 726/2004)**

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
17.3.2009	Dynepo	Shire Pharmaceutical Contracts Ltd Hampshire International Business Park, Chineham, Basingstoke Hampshire RG24 8EP UNITED KINGDOM	EU/1/02/211/001-005 EU/1/02/211/010-012	19.3.2009

— Issuing of a marketing authorization (Article 38 of Regulation (EC) No ⁽¹⁾ 726/2004): 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
17.3.2009	BTVPUR Alsap 8	Bluetongue virus Serotype 8 Antigen	MERIAL 29 avenue Tony Garnier 69007 LYON FRANCE	EU/2/09/094/001-005	Suspension for injection	Q104AA02 Q102AA08	19.3.2009

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004): 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
6.3.2009	Econor	Novartis Animal Health Austria GmbH Biochemiestrasse 10 6250 Kundl ÖSTERREICH	EU/2/98/010/004-006 EU/2/98/010/017-018 EU/2/98/010/021-024	10.3.2009
12.3.2009	Novem	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein DEUTSCHLAND	EU/2/04/042/003-004	16.3.2009
18.3.2009	Aivlosin	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS UNITED KINGDOM	EU/2/04/044/001-008	20.3.2009
23.3.2009	Equilis Prequenza Te	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/05/057/001-004	25.3.2009
23.3.2009	Equilis Prequenza	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/05/056/001-004	25.3.2009
25.3.2009	Quadrisol	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/97/005/002-004 EU/2/97/005/006-009	27.3.2009

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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