

**Summary of Community decisions on marketing authorisations in respect of medicinal products
from 1 November 2009 to 30 November 2009**

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

(2010/C 22/02)

— 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
4.11.2009	Repaglinide Krka	Repaglinide	KRKA, d. d. Novo mesto Šmarješka cesta 6 SI-8501 Novo mesto SLOVENIJA	EU/1/09/579/001-018	Tablet	A10B X02	6.11.2009
4.11.2009	Copalia HCT	amlodipine besylate/ valsartan/hydrochlorothiazide	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/575/001-060	Film-coated tablet	C09DX01	6.11.2009
4.11.2009	Dafiro HCT	amlodipine besylate/ valsartan/hydrochlorothiazide	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/574/001-060	Film-coated tablet	C09DX01	6.11.2009
26.11.2009	Multaq	dronedarone	Sanofi-Aventis 174 avenue de France 75013 Paris FRANCE	EU/1/09/591/001-004	Film-coated tablet	Not applicable	1.12.2009
26.11.2009	Irbesartan/Hydrochlorothiazide Teva	hydrochlorothiazide	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/583/001-072	Film-coated tablet	C09D A04	1.12.2009

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

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30.11.2009	Sildenafil Teva	Sildenafil	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/584/001-018	Film-coated tablet	G04BE03	2.12.2009
30.11.2009	Nevirapine Teva	nevirapine	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/598/001-004	Tablet	J05AG01	2.12.2009
30.11.2009	Hirobriz Breezhaler	Indacaterol	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/594/001-010	Inhalation powder	Not applicable	2.12.2009
30.11.2009	Onbrez Breezhaler	Indacaterol	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/593/001-010	Inhalation powder	Not applicable	2.12.2009
30.11.2009	Oslif Breezhaler	Indacaterol	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/586/001-010	Inhalation powder	Not applicable	2.12.2009
30.11.2009	Zutectra	Human Hepatitis B Immunoglobulin	Biotest Pharma GmbH Landsteinerstr. 5 63303 Dreieich DEUTSCHLAND	EU/1/09/600/001	Solution for injection	J06BB04	2.12.2009

— **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
4.11.2009	Intelence	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	6.11.2009
4.11.2009	Optisulin	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/00/133/001-032	6.11.2009
4.11.2009	Lantus	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/00/134/001-037	6.11.2009
4.11.2009	Ketek	Aventis Pharma S.A. 20 avenue Raymond Aron 92160 Antony FRANCE	EU/1/01/191/001-005	6.11.2009
4.11.2009	Osseor	Les Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/04/287/001-006	6.11.2009
4.11.2009	Protelos	Les Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/04/288/001-006	6.11.2009
5.11.2009	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	10.11.2009
5.11.2009	Tyverb	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/440/001-002	9.11.2009
5.11.2009	Pre-pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/478/001	9.11.2009
5.11.2009	Celsentri	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/07/418/001-010	9.11.2009
5.11.2009	Invega	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/07/395/001-095	9.11.2009

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
5.11.2009	Foscan	Biolitec Pharma Ltd United Drug House Magna Drive Dublin 24 IRELAND	EU/1/01/197/003-005	9.11.2009
6.11.2009	Fosavance	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/05/310/001-009	10.11.2009
9.11.2009	Januvia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/383/001-018	11.11.2009
11.11.2009	Celvapan	Baxter AG Industriestraße 67 1221 Wien ÖSTERREICH	EU/1/08/506/001	12.11.2009
11.11.2009	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina 1 53100 Siena SI ITALIA	EU/1/07/385/001-002 EU/1/07/385/004	12.11.2009
11.11.2009	Pandemrix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/452/001	12.11.2009
11.11.2009	Insuman	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/97/030/028-195	13.11.2009
11.11.2009	PegIntron	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/00/131/001-050	13.11.2009
11.11.2009	Soliris	Alexion Europe S.A.S. 25 boulevard de l'Amiral Bruix 75016 Paris FRANCE	EU/1/07/393/001	13.11.2009
11.11.2009	Rebetol	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/99/107/001-005	13.11.2009
12.11.2009	Intence	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	17.11.2009

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12.11.2009	IntronA	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/99/127/001-044	17.11.2009
12.11.2009	ViraferonPeg	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/00/132/001-050	17.11.2009
19.11.2009	IntronA	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/99/127/031-039	23.11.2009
19.11.2009	Clopidogrel Pharma	Teva Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND HCS bvba, H. Kennisstraat 53 2650 Edegem BELGIË	EU/1/09/561/001-009	23.11.2009
20.11.2009	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square The Forbury, Reading Berkshire RG1 3EB UNITED KINGDOM	EU/1/07/392/001-002	18.12.2009
20.11.2009	Bondronat	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/96/012/004 EU/1/96/012/009-013	24.11.2009
20.11.2009	Ebixa	H. Lundbeck A/S Ottliavej 9 2500 Valby DANMARK	EU/1/02/219/001-003 EU/1/02/219/005-049	24.11.2009
20.11.2009	Mycamine	Astellas Pharma Europe B.V. Elisabethhof 19 2353 EW Leiderdorp NEDERLAND	EU/1/08/448/001-002	24.11.2009
20.11.2009	NeoRecormon	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/97/031/019-046	24.11.2009
20.11.2009	MabCampath	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND	EU/1/01/193/001-002	24.11.2009

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20.11.2009	Somavert	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/02/240/001-004	24.11.2009
20.11.2009	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/03/267/001-010	24.11.2009
20.11.2009	Xeristar	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/04/297/001-008	24.11.2009
20.11.2009	Regranex	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/99/101/001	24.11.2009
20.11.2009	Ziagen	Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/99/112/001-002	24.11.2009
20.11.2009	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/04/296/001-009	24.11.2009
20.11.2009	Angiox	The Medicines Company UK Ltd 115 L Milton Park Abingdon Oxfordshire OX14 4SA UNITED KINGDOM	EU/1/04/289/001-002	24.11.2009
20.11.2009	Agenerase	Glaxo Group Limited Glaxo Wellcome House Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/00/148/001-004	24.11.2009
20.11.2009	RoActemra	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/08/492/001-006	24.11.2009
23.11.2009	Nexavar	Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND	EU/1/06/342/001	25.11.2009
23.11.2009	Noxafil	SP Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/05/320/001	25.11.2009

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23.11.2009	Pritor	Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND	EU/1/98/089/001-022	25.11.2009
23.11.2009	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/05/315/001-002	26.11.2009
23.11.2009	Exjade	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/356/001-009	25.11.2009
23.11.2009	Cervarix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/07/419/001-012	25.11.2009
23.11.2009	Trizivir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/00/156/002-003	25.11.2009
23.11.2009	Telzir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/04/282/001-002	25.11.2009
23.11.2009	Azilect	Teva Pharma GmbH Kandelstrasse 10 79199 Kirchzarten DEUTSCHLAND	EU/1/04/304/001-007	25.11.2009
23.11.2009	Invega	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/07/395/001-095	25.11.2009
23.11.2009	Puregon	Organon N.V. Kloosterstraat 6 Postbus 20 5340 BH Oss NEDERLAND	EU/1/96/008/001-041	25.11.2009
23.11.2009	Kinzalmono	Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND	EU/1/98/091/001-014	25.11.2009
23.11.2009	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/98/090/001-020	26.11.2009
23.11.2009	Kaletra	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/01/172/001-007	25.11.2009

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24.11.2009	Synagis	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/99/117/001-002	26.11.2009
24.11.2009	alli	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/401/007-010	26.11.2009
25.11.2009	Kivexa	Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/04/298/001-003	27.11.2009
26.11.2009	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/99/126/001-021	1.12.2009
26.11.2009	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/99/126/001-021	1.12.2009
26.11.2009	Diacomit	Biocodex 7 avenue Gallieni 94250 Gentilly FRANCE	EU/1/06/367/001-012	1.12.2009
26.11.2009	Intelence	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	1.12.2009
26.11.2009	Abseamed	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 58638 Iserlohn DEUTSCHLAND	EU/1/07/412/021-026	1.12.2009
27.11.2009	Pandemrix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/452/001	30.11.2009
27.11.2009	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina 1 53100 Siena SI ITALIA	EU/1/07/385/001-002 EU/1/07/385/004	30.11.2009
30.11.2009	Velcade	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/04/274/001-002	2.12.2009

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30.11.2009	Champix	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/06/360/001-013	2.12.2009
30.11.2009	Adcirca	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/08/476/001-006	2.12.2009
30.11.2009	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron 92165 Antony Cedex FRANCE	EU/1/07/384/003-004	2.12.2009
30.11.2009	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron 92165 Antony Cedex FRANCE	EU/1/95/002/003-004	2.12.2009

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

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
11.11.2009	Irbesartan BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/375/001-033	13.11.2009
11.11.2009	Irbesartan HCT BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/369/001-028	13.11.2009
12.11.2009	Clopidogrel BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/08/464/001-019	17.11.2009
26.11.2009	Paxene	Norton Healthcare Limited Albert Basin Royal Docks London E16 2QJ UNITED KINGDOM	EU/1/99/113/001-004	10.12.2009

— Issuing of a marketing authorisation (Article 38 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
4.11.2009	Zolvix	Monepantel	Novartis Healthcare A/S Lyngbyvej 172 2100 Copenhagen DANMARK	EU/2/09/101/001-010	Oral solution	QP52AX09	6.11.2009

— **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
18.11.2009	Dexdomitor	Orion Corporation Orionintie 1 FI-02200 Espoo SUOMI/FINLAND	EU/2/02/033/001-002	20.11.2009
19.11.2009	Improvac	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/2/09/095/001-003	23.11.2009
20.11.2009	Metacam	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein DEUTSCHLAND	EU/2/97/004/026 EU/2/97/004/033-034	24.11.2009
23.11.2009	Halocur	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/99/013/001-002	25.11.2009

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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