IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION

Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 October 2009 to 31 October 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 288/01)

— 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
1.10.2009	Onglyza	Saxagliptin	Bristol Myers Squibb/Astra-Zeneca EEIG, Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/09/545/001-010	Film-coated tablet	A10BH03	5.10.2009
1.10.2009	Cimzia	certolizumab pegol	UCB Pharma SA., Allée de la Recherche 60, 1070 Bruxelles, Belgique/Research-dreef, 60, Brussel 1070, België	EU/1/09/544/001-002	Solution for injection	L04AB05	6.10.2009
1.10.2009	Simponi	golimumab	Centocor B.V., Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/09/546/001-004	Solution for injection in pre-filled pen	L04AB06	6.10.2009

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

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
5.10.2009	ChondroCelect	Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins	TiGenix NV, Romeinse straat 12/2, B-3001 Leuven, België	EU/1/09/563/001	Implantation suspension	Non applicable	7.10.2009
14.10.2009	Enyglid	Repaglinide	KRKA, d. d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/580/001-018	Tablet	A10B X02	16.10.2009
15.10.2009	Resolor	prucalopride	Movetis NV, Veedijk 58, B-2300 Turnhout, België	EU/1/09/581/001-002	Film-coated tablets	A03AE04	19.10.2009
15.10.2009	Imprida HCT	amlodipine besylate / valsartan / hydrochloro-thiazide	Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/570/001-060	Film-coated tablet	C09DX01	19.10.2009
16.10.2009	Clopidogrel MYLAN Pharma	Clopidogrel	Mylan S.A.S, 117 allee des Parcs, 69800 Saint Priest, France	EU/1/09/568/001-018	Film-coated tablet	B01AC-04	20.10.2009
16.10.2009	PANDEMIC INFLUENZA VACCINE H5N1 BAXTER	Pandemic influenza vaccine (H5N1 whole virion, Vero cell derived, inactivated)	Baxter AG, Industriestraße 67, A - 1221 Wien, Österreich	EU/1/09/571/001	Suspension for injection	J07BB01	20.10.2009
16.10.2009	Exforge HCT	amlodipine besylate / valsartan / hydrochloro-thiazide	Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/569/001-060	Film-coated tablet	C09DX01	20.10.2009
16.10.2009	ALENDRONATE SODIUM AND COLECALCIFEROL, MSD	alendronic acid / colecalciferol	Merck Sharp & Dohme Ltd., Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572/001-009	Tablet	M05BB03	20.10.2009
19.10.2009	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) Glaxo-SmithKline Biologicals	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14	GlaxoSmithKline Biologicals s.a., rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/578/001	Suspension and Emulsion for emulsion for injection	J07BB02	21.10.2009
19.10.2009	Foclivia	A/Viet Nam/1194/2004 (H5N1) virus surface inactivated antigen	Novartis Vaccines and Diag-nostics S.r.l., Via Fiorentina, 1 - Siena, Italia	EU/1/09/577/001-004	Suspension for injection	J07BB02	21.10.2009

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23.10.2009	Lamivudine Teva	Lamivudine	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/566/001-005	Film-coated tablet	J05AF05	27.10.2009
23.10.2009	Biopoin	epoetin theta	CT Arzneimittel GmbH, Lengeder Straße 42a, D-13407 Berlin, Deutschland	EU/1/09/565/001-028	Solution for injection	B03XA01	27.10.2009
23.10.2009	ARCALYST	Rilonacept	Regeneron UK Limited, 40 Bank Street, E14 5DS London, United Kingdom	EU/1/09/582/001	Powder and solvent for solution for injection	L04AC04	27.10.2009
23.10.2009	ILARIS	Canakinumab	Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/564/001-002	Powder for solution for injection	L04AC08	27.10.2009
29.10.2009	Eporatio	epoetin theta	ratiopharm GmbH, Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/09/573/001-028	Solution for injection	B03XA01	2.11.2009
30.10.2009	Irbesartan Teva	Irbesartan	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/576/001-039	Film-coated tablet	C09C A04	4.11.2009

— **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
1.10.2009	Epoetin alfa Hexal	Hexal AG., Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/07/411/021-026	5.10.2009
1.10.2009	Mixtard	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/231/001-037	5.10.2009
1.10.2009	Protaphane	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/234/001-017	5.10.2009
1.10.2009	Insulatard	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/233/001-017	5.10.2009
1.10.2009	Actrapid	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/230/001-017	5.10.2009
1.10.2009	Actraphane	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/229/001-037	6.10.2009
1.10.2009	Binocrit	Sandoz GmbH, Biochemiestrasse 10, Kundl 6250, Österreich	EU/1/07/410/021-026	5.10.2009
2.10.2009	Tasmar	Meda AB, Pipers väg 2A, Solna 170 09, Sverige	EU/1/97/044/001-008	6.10.2009
6.10.2009	CELVAPAN	Baxter AG, Industriestraße 67, 1221 Wien, Österreich	EU/1/08/506/001	8.10.2009
7.10.2009	Agenerase	Glaxo Group Limited, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/00/148/001-004	9.10.2009
7.10.2009	IntronA	Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/99/127/031-039	9.10.2009
8.10.2009	Mirapexin	Boehringer Ingelheim International GmbH, Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/97/051/013-027	12.10.2009
8.10.2009	Sifrol	Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/050/013-027	12.10.2009
8.10.2009	Nplate	Amgen Europe B.V., Minervum 7061, 4817 ZK Breda, Nederland	EU/1/08/497/001-004	12.10.2009

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8.10.2009	Circadin	RAD Neurim Pharmaceuticals EEC Limited, One Forbury Square, The Forbury, Reading, Berkshire RG1 3EB, United Kingdom	EU/1/07/392/001-002	12.10.2009
13.10.2009	NovoMix	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/00/142/004-005 EU/1/00/142/009-022	15.10.2009
13.10.2009	Olanzapine Neopharma	Neopharma Limited, 57 High Street, Odiham, Hampshire RG29 1LF, United Kingdom	EU/1/07/426/001-011	15.10.2009
13.10.2009	CellCept	Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/005/001-006	15.10.2009
13.10.2009	Kinzalkomb	Bayer Schering Pharma AG, D-13342 Berlin, Deutschland	EU/1/02/214/001-015	15.10.2009
14.10.2009	alli	Glaxo Group Limited, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/401/001-006	16.10.2009
14.10.2009	Onsenal	Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/03/259/001-006	16.10.2009
14.10.2009	PritorPlus	Bayer Schering Pharma AG, 13342 Berlin, Deutschland	EU/1/02/215/001-021	16.10.2009
14.10.2009	Ammonaps	Swedish Orphan International AB, Drottninggatan 98, 111 60 Stockholm, Sverige	EU/1/99/120/001-004	19.10.2009
15.10.2009	Nexavar	Bayer Schering Pharma AG, 13342 Berlin, Deutschland	EU/1/06/342/001	19.10.2009
16.10.2009	Helixate NexGen	Bayer Schering Pharma AG, 13342 Berlin, Deutschland	EU/1/00/144/001-004	20.10.2009
16.10.2009	Aptivus	Boehringer Ingelheim International GmbH, Binger Strasse 173- 55216 Ingelheim am Rhein, Deutschland	EU/1/05/315/001-002	20.10.2009
16.10.2009	KOGENATE Bayer	Bayer Schering Pharma AG, 13342 Berlin, Deutschland	EU/1/00/143/001-011	20.10.2009
19.10.2009	Thalidomide Celgene	Celgene Europe Limited, Riverside House, Riverside Walk, Windsor SL4 1NA, United Kingdom	EU/1/08/443/001	21.10.2009
19.10.2009	Ribavirin Teva Pharma BV	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/527/001-016	21.10.2009

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19.10.2009	Revlimid	Celgene Europe Limited, Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom	EU/1/07/391/001-004	21.10.2009
19.10.2009	Prepandrix	GlaxoSmithKline Biologicals s.a., rue de l'Institut 89, Rixensart, 1330 Belgique	EU/1/08/453/002	21.10.2009
19.10.2009	Wilzin	Orphan Europe S.a.r.l., Immeuble Le Wilson, 70 Avenue du Général de Gaulle, 92800 Puteaux, France	EU/1/04/286/001-002	21.10.2009
19.10.2009	Olanzapine Teva	Teva Pharma B.V., Computerweg 10, DR Utrecht 3542,Nederland	EU/1/07/427/001-057	21.10.2009
20.10.2009	Vidaza	Celgene Europe Ltd, Riverside House, Riverside Walk, Windsor, SL4 1NA, United Kingdom	EU/1/08/488/001	22.10.2009
21.10.2009	Xarelto	Bayer Schering Pharma AG, 13342 Berlin, Deutschland	EU/1/08/472/001-008	23.10.2009
21.10.2009	Metalyse	Boehringer Ingelheim International GmbH, Binger Strasse 173- 55216 Ingelheim am Rhein, Deutschland	EU/1/00/169/004-006	23.10.2009
21.10.2009	Filgrastim Hexal	HEXAL AG, Industriestrasse 25, 83607 Holzkirchen, Deutschland	EU/1/08/496/001-008	26.10.2009
21.10.2009	Zarzio	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/08/495/001-008	23.10.2009
23.10.2009	Rebif	Merck Serono Europe Limited, 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/98/063/001-010	27.10.2009
23.10.2009	Prezista	Janssen-Cilag International NV, Turnhoutseweg, 30 - 2340 Beerse – België	EU/1/06/380/001-005	27.10.2009
23.10.2009	Olanzapine Mylan	Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/08/475/001-034	27.10.2009
23.10.2009	Norvir	Abbott Laboratories Ltd, Queenborough, Kent ME11 5EL, United Kingdom	EU/1/96/016/001 EU/1/96/016/003-004	27.10.2009

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23.10.2009	PEGASYS	Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/221/001-010	27.10.2009
23.10.2009	Invanz	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/02/216/001-002	27.10.2009
23.10.2009	Procoralan	Les Laboratoires Servier, 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/05/316/001-014	27.10.2009
23.10.2009	Teslascan	GE Healthcare AS, Nycoveien 1-2, P.O.Box 4220 Nydalen, N-0401 Oslo, Norway	EU/1/97/040/001-002	27.10.2009
23.10.2009	Vistide	Gilead Sciences International Limited, Cambridge, CB21 6GT, United Kingdom	EU/1/97/037/001	27.10.2009
23.10.2009	RotaTeq	Sanofi Pasteur MSD, SNC, 8, rue Jonas Salk, Lyon 69007, France	EU/1/06/348/001-002	27.10.2009
23.10.2009	Tamiflu	Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-004	27.10.2009
23.10.2009	Corlentor	Les Laboratoires Servier, 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/05/317/001-014	27.10.2009
23.10.2009	Neulasta	Amgen Europe B.V., Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227/001-004	27.10.2009
23.10.2009	Ellaone	Laboratoire HRA Pharma, 15, rue Béranger, 75003 Paris, France	EU/1/09/522/001	27.10.2009
28.10.2009	Xelevia	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382/001-018	30.10.2009
28.10.2009	TESAVEL	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435/001-018	30.10.2009
28.10.2009	Pradaxa	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-008	2.11.2009

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28.10.2009	Aranesp	Amgen Europe B.V., Minervum 7061, 4817 ZK Breda, Nederland	EU/1/01/185/001-022 EU/1/01/185/031-099	30.10.2009
28.10.2009	Zerit	Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/96/009/001-009	30.10.2009
28.10.2009	Arava	Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Deutschland	EU/1/99/118/001-010	30.10.2009
28.10.2009	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	30.10.2009
28.10.2009	Myozyme	Genzyme Europe B.V., Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/06/333/001-003	2.11.2009
28.10.2009	SUTENT	Pfizer Ltd, Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/347/001-008	30.10.2009
28.10.2009	Integrilin	Glaxo Group Ltd, Greenford, Middlesex, UB6 ONN, United Kingdom	EU/1/99/109/001-002	30.10.2009
28.10.2009	BeneFIX	Wyeth Europa Ltd., Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/97/047/001-007	30.10.2009
28.10.2009	RoActemra	Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	30.10.2009
28.10.2009	Beromun	Boehringer Ingelheim International GmbH, Binger Strasse 173- 55216 Ingelheim am Rhein, Deutschland	EU/1/99/097/001	2.11.2009
28.10.2009	Epivir	Glaxo Group Ltd., Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/96/015/001-005	30.10.2009
28.10.2009	IXIARO	Intercell AG, Campus Vienna Biocenter 3 A-1030 Wien, Österreich	EU/1/08/501/001-002	30.10.2009
28.10.2009	Efficib	Merck Sharp & Dohme Ltd., Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457/001-016	30.10.2009

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28.10.2009	Janumet	Merck Sharp & Dohme Ltd., Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455/001-016	30.10.2009
28.10.2009	Noxafil	SP Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/05/320/001	30.10.2009
28.10.2009	Velcade	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	30.10.2009
28.10.2009	Zostavax	Sanofi Pasteur MSD, SNC, 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/341/001-013	30.10.2009
28.10.2009	Velmetia	Merck Sharp & Dohme Ltd., Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456/001-016	30.10.2009
29.10.2009	Sebivo	Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/388/001-003	2.11.2009
29.10.2009	ADROVANCE	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/364/001-009	2.11.2009
29.10.2009	Remicade	Centocor B.V., Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	2.11.2009
29.10.2009	INOmax	INO Therapeutics AB, SE-181 81 Lidingö, Sverige	EU/1/01/194/001-002	3.11.2009
30.10.2009	Xagrid	Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, Basingstoke, Hampshire RG24 8EP, United Kingdom	EU/1/04/295/001	4.11.2009
30.10.2009	Zalasta	KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/07/415/001-056	4.11.2009
30.10.2009	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Deutschland	EU/1/06/368/001-168	4.11.2009

— **Lift of suspension of a marketing authorization (Article 20 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
8.10.2009	Optison	GE Healthcare AS, Nycoveien 1-2, P.O.Box 4220 Nydalen, N-0401 Oslo, Norway	EU/1/98/065/001-002	12.10.2009

— **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
1.10.2009	Oxyglobin	Biopure Netherlands B.V., Parnassustoren, Locatellikade 1, 1076 AZ Amsterdam, Nederland	EU/2/99/015/001-002	5.10.2009
1.10.2009	Stronghold	Pfizer Ltd, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/99/014/001-012	5.10.2009
6.10.2009	Nobilis Influenza H5N2	Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/06/061/001-004	8.10.2009
8.10.2009	Naxcel	Pfizer Ltd, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/05/053/003	12.10.2009
8.10.2009	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited, Loughrea, Co. Galway, IRELAND	EU/2/07/078/005-008	12.10.2009
8.10.2009	Meloxidyl	CEVA SANTE ANIMALE, Z.I. la Ballastière, 33500 Libourne, France	EU/2/06/070/004	12.10.2009
21.10.2009	Suprelorin	VIRBAC S.A., 1ère Avenue 2065 m L.I.D. - 06516 Carros – France	EU/2/07/072/001-002	23.10.2009
30.10.2009	Easotic	VIRBAC S.A., 1ère Avenue 2065 m L.I.D. - 06516 Carros – France	EU/2/08/085/001	4.11.2009

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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