Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 September 2006 to 30 September 2006

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

(2006/C 259/04)

— 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
20.9.2006	Gardasil	Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/06/357/001-017	Suspension for injection	J07BM1	22.9.2006
20.9.2006	Silgard	Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/06/358/001-017	Suspension for injection	J07BM1	22.9.2006
20.9.2006	Luminity	Perflutren	Bristol-Myers Squibb Pharma Belgium Sprl Chaussée de la Hulpe 185 B-1170 Brussels	EU/1/06/361/001	Solution for dispersion for injection or infusion	V08D A04	22.9.2006
26.9.2006	Suboxone	buprenorphine/ naloxone	Schering Plough Europ Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-180 Brussel	EU/1/06/359/001-004	Sublingual tablet	N07B C51	28.9.2006
26.9.2006	Champix	varenicline tartrate	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/06/360/001-010	Film-coated tablet	N07BA03	28.9.2006

[1] OJ L 136 of 30 April 2004, page 1.

— **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
5.9.2006	Alpheon	BioPartners GmbH Eisenstrasse 3 D-65428 Rüsselsheim	Non applicable	7.9.2006

— **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
1.9.2006	Aldara	Laboratoires 3M Santé Boulevard de l'Oise F-95029 Cergy Pontoise Cedex	EU/1/98/080/001	5.9.2006
1.9.2006	Angiox	The Medicines Company UK Ltd Suite B Park House, 11 Milton Park Abingdon Oxfordshire OX14 4RS United Kingdom	EU/1/04/289/001-002	7.9.2006
1.9.2006	Rebif	Serono Europe Ltd. 56, Marsh Wall London E14 9TP United Kingdom	EU/1/98/063/001-007	7.9.2006
1.9.2006	Iscover	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 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	11.9.2006
1.9.2006	Fasturtec	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/00/170/001-002	7.9.2006
1.9.2006	Neoclarityn	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/00/161/001-034	7.9.2006
1.9.2006	Replagal	TKT Europe AB Rinkebyvägen 11B S-182 36 Danderyd	EU/1/01/189/001-006	7.9.2006
1.9.2006	Liprolog	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/01/195/003 EU/1/01/195/006 EU/1/01/195/011 EU/1/01/195/014	7.9.2006
1.9.2006	Fabrazyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/01/188/001-006	7.9.2006
1.9.2006	Azomyr	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/00/157/001-034	7.9.2006

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1.9.2006	Aerius	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/00/160/001-035	6.9.2006
1.9.2006	Remicade	Centocor B.V. Einsteinweg 101 2333 CB Leiden Nederland	EU/1/99/116/001-003	6.9.2006
1.9.2006	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 174, avenue de France F-75013 Paris	EU/1/98/069/001a-001b EU/1/98/069/002a-002b EU/1/98/069/003a-003b EU/1/98/069/004a-004b	6.9.2006
1.9.2006	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main	EU/1/00/134/030-037	6.9.2006
1.9.2006	Viramune	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein	EU/1/97/055/001-003	6.9.2006
1.9.2006	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/99/110/001-009	6.9.2006
1.9.2006	Betaferon	Schering Aktiengesellschaft D-13342 Berlin	EU/1/95/003/003-006	6.9.2006
1.9.2006	Viread	Gilead Sciences International Limited Cambridge CB1 6GT United Kingdom	EU/1/01/200/001	7.9.2006
1.9.2006	Stocrin	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/99/111/001-009	6.9.2006
1.9.2006	Rebetol	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/99/107/001-005	7.9.2006
1.9.2006	Humalog	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/96/007/005 EU/1/96/007/008 EU/1/96/007/016 EU/1/96/007/024 EU/1/96/007/027	7.9.2006
1.9.2006	Apidra	Sanofi-Aventis Deutschland GmbH Brueningstrasse 50 D-65926 Frankfurt am Main	EU/1/04/285/001-036	7.9.2006
1.9.2006	ViraferonPeg	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/00/132/001-050	7.9.2006

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1.9.2006	IntronA	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/99/127/001-044	8.9.2006
1.9.2006	Viraferon	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/99/128/001-037	8.9.2006
1.9.2006	PegIntron	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles/ Stallestraat, 73 B-1180 Brussel	EU/1/00/131/001-050	8.9.2006
1.9.2006	Invanz	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/02/216/001-002	8.9.2006
7.9.2006	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU United Kingdom	EU/1/04/276/001-035	12.9.2006
7.9.2006	Lyrica	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/04/279/001-035	12.9.2006
7.9.2006	Rapamune	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/01/171/001 EU/1/01/171/007-012	12.9.2006
7.9.2006	Avonex	Biogen Idec Ltd 5 Roxborough Way Foundation Park, Maidenhead Berkshire SL6 3UD United Kindgom	EU/1/97/033/001-003	12.9.2006
7.9.2006	Levviax	Aventis Pharma S.A. 20, Avenue Raymond Aron F-92160 Antony	EU/1/01/192/001-005	12.9.2006
7.9.2006	Ketek	Aventis Pharma S.A. 20, Avenue Raymond Aron F-92160 Antony	EU/1/01/191/001-005	12.9.2006
7.9.2006	Zonegran	Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/04/307/001-010	12.9.2006

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12.9.2006	Arixtra	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/206/018-020	15.9.2006
12.9.2006	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/05/323/001-013	14.9.2006
12.9.2006	Tamiflu	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/02/222/001-002	14.9.2006
12.9.2006	Quixidar	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/207/018-020	15.9.2006
12.9.2006	Zyprexa Velotab	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/99/125/001-008	14.9.2006
12.9.2006	Zyprexa	Eli Lilly Nederland BV 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/1/96/022/019-022	14.9.2006
13.9.2006	Zyprexa Velotab	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/99/125/001-008	15.9.2006
13.9.2006	Zyprexa	Eli Lilly Nederland BV 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/1/96/022/019-022	15.9.2006
14.9.2006	Glivec	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/01/198/001-013	18.9.2006
14.9.2006	Prialt	Elan Pharma International Ltd WIL House Shannon Business Park Shannon County Clare Ireland Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/04/302/001-004	18.9.2006 18.9.2006

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18.9.2006	DaTSCAN	GE Healthcare Limited Little Chalfont Bucks HP7 9NA United Kingdom	EU/1/00/135/001-002	20.9.2006
21.9.2006	Fuzeon	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/03/252/001-003	25.9.2006
21.9.2006	Glivec	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/01/198/001-013	25.9.2006
26.9.2006	Aclasta	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/05/308/001-002	28.9.2006
26.9.2006	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/99/126/013-018	28.9.2006
29.9.2006	Cancidas	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/01/196/001-003	3.10.2006

— **Issuing 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	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
1.9.2006	Poulvac FluFend H5N3 RG	Inactivated recombinant avian influenza virus of H5N3 subtype (strain rg-A/ck/VN/C58/04) 256 — 4046 HA Units	Fort Dodge Animal Health Ltd Flanders Road Hedge End Southampton SO30 4QH United Kingdom	EU/2/06/060/001-002	Emulsion for injection	QI01AA23	7.9.2006
1.9.2006	Nobilis Influenza H5N2	Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥ 6.0 log2 as tested according to the potency test.	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Nederland	EU/2/06/061/001-004	Emulsion for injection	QI01AA23	7.9.2006
29.9.2006	Cerenia	Maropitant	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/2/06/062/001-004 EU/2/06/062/005	Tablet Solution for injection	QA04AD90	3.10.2006

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

The European Medicines Agency
7, Westferry Circus, Canary Wharf
LONDON E14 4HB
United Kingdom