Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 September 2008 to 30 September 2008

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

(2008/C 276/02)

— 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
12.9.2008	Oprymea	Pramipexole	KRKA, d.d. Šmarješka cesta 6 SLO-8501 Novo mesto	EU/1/08/469/001-025	Tablet	NO4BC05	15.9.2008
15.9.2008	Tevagrastim	Filgrastim	Teva Generics GmbH Kandelstr. 10 D-79199 Kirchzarten	EU/1/08/445/001-008	Solution for injection or infusion	L03AA02	17.9.2008
15.9.2008	Biograstim	Filgrastim	CT Arzneimittel GmbH Lengeder Straße 42a D-13407 Berlin	EU/1/08/450/001-008	Solution for injection or infusion	L03AA02	17.9.2008
15.9.2008	Ratiograstim	Filgrastim	ratiopharm GmbH Graf-Arco-Straße 3 D-89079 Ulm	EU/1/08/444/001-008	Solution for injection or infusion	L03AA02	17.9.2008
15.9.2008	Filgrastim ratiopharm	Filgrastim	ratiopharm GmbH Graf-Arco-Straße 3 D-89079 Ulm	EU/1/08/449/001-008	Solution for injection or infusion	L03AA02	17.9.2008
26.9.2008	Prepandemic influenza vaccine (H5N1) (split virion inactivated adjuvanted) GlaxoSmithKline Biologicals	Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14	GlaxoSmithKline Biologicals S.A. rue de l'Institut, 89 B-1330 Rixensart	EU/1/08/478/001	Suspension and emulsion for emulsion for injection	J07BB02	30.9.2008
30.9.2008	Xarelto	Rivaroxaban	Bayer HealthCare AG D-51368 Leverkusen	EU/1/08/472/001-008	Film-coated tablet	B01AX06	2.10.2008

[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
1.9.2008	Aranesp	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/01/185/001-073	3.9.2008
1.9.2008	Adenuric	Beaufour Ipsen Pharma 24, rue Erlanger F-75781 Paris Cedex 16	EU/1/08/447/001-004	3.9.2008
		Ipsen Manufacturing Ireland Ltd (IMIL) Blanchardstown Industrial Park Snugboro Road Dublin 15 Ireland		3.9.2008
1.9.2008	Rotarix	GlaxoSmithKline Biologicals s.a. rue de l'Institut, 89 B-1330 Rixensart	EU/1/05/330/001-011	3.9.2008
1.9.2008	Zostavax	Sanofi Pasteur MSD SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/06/341/001-013	3.9.2008
2.9.2008	Ziagen	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/99/112/001-002	4.9.2008
2.9.2008	Lucentis	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/06/374/001	4.9.2008
2.9.2008	Olanzapine Neopharma	Neopharma Limited 57 High Street Odiham Hampshire RG29 1LF United Kingdom	EU/1/07/426/001-011	4.9.2008
2.9.2008	SonoVue	Bracco International B.V. Strawinskylaan 3051 1077 ZX Amsterdam Nederland	EU/1/01/177/002	4.9.2008
2.9.2008	Gardasil	Sanofi Pasteur MSD SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/06/357/001-021	5.9.2008
2.9.2008	Viramune	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/97/055/001-003	4.9.2008
2.9.2008	Ventavis	Bayer Schering Pharma AG Müllerstraße 170-178 D-13342 Berlin	EU/1/03/255/001-006	4.9.2008
2.9.2008	Silgard	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/06/358/001-021	4.9.2008

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2.9.2008	Cetrotide	Serono Europe Limited 56 Marsh Wall London E14 9TP United Kingdom	EU/1/99/100/001-003	5.9.2008
2.9.2008	Olanzapine Teva -	Teva Pharma B.V. Computerweg 10 DR Utrecht 3542 Nederland	EU/1/07/427/001-057	4.9.2008
2.9.2008	Elaprase	Shire Human Genetic Therapies AB Rinkebyvägen 11B S-182 36 Danderyd	EU/1/06/365/001-003	4.9.2008
3.9.2008	Tysabri	Elan Pharma International Ltd Monksland Athlone County Westmeath Ireland	EU/1/06/346/001	8.9.2008
3.9.2008	Comtess	Orion Corporation Orionintie 1 FI-02200 Espoo	EU/1/98/082/001-003 EU/1/98/082/005	8.9.2008
3.9.2008	Aldara	Meda AB Pipers väg 2A S-170 73 Solna	EU/1/98/080/001	5.9.2008
3.9.2008	Tamiflu	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/02/222/001-004	5.9.2008
3.9.2008	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/97/051/001-006 EU/1/97/051/009-012	5.9.2008
3.9.2008	Aldara	Meda AB Pipers väg 2A S-170 73 Solna	EU/1/98/080/001	5.9.2008
3.9.2008	Comtan	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/98/081/001-004	8.9.2008
3.9.2008	Cialis	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/02/237/001-008	5.9.2008
5.9.2008	Mircera	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/07/400/017-021	9.9.2008
5.9.2008	Herceptin	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/00/145/001	9.9.2008

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5.9.2008	Puregon	Organon N.V. Kloosterstraat 6 Postbus 20 5340 BH Oss Nederland	EU/1/96/008/038-041	9.9.2008
5.9.2008	Epivir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/96/015/001-005	9.9.2008
8.9.2008	Evra	Janssen-Cilag International NV Turnhoutseweg, 30 B-2340 Beerse	EU/1/02/223/001-003	10.9.2008
9.9.2008	Herceptin	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/00/145/001	11.9.2008
12.9.2008	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	15.9.2008
15.9.2008	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH United Kingdom	EU/1/99/110/001-009	17.9.2008
15.9.2008	Glubrava	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/07/421/001-009	17.9.2008
15.9.2008	Stalevo	Orion Corporation Orionintie 1 FI-02200 Espoo	EU/1/03/260/001-023	17.9.2008
16.9.2008	Combivir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/98/058/001-002	18.9.2008
17.9.2008	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main	EU/1/00/133/001-008	19.9.2008
17.9.2008	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main	EU/1/00/134/001-037	19.9.2008
22.9.2008	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/03/261/001-003	24.9.2009
22.9.2008	Emend	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/03/262/001-008	24.9.2008

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26.9.2008	Aclasta	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/05/308/001-002	30.9.2008
26.9.2008	Thelin	Encysive (UK) Limited Alder Castle House 10 Noble Street London EC2V 7QJ United Kingdom	EU/1/06/353/001-005	30.9.2008
29.9.2008	Mycamine	Astellas Pharma Europe B.V. Elisabethhof 19 2353 EW Leiderdorp Nederland	EU/1/08/448/001-002	1.10.2008
		Astellas Pharma GmbH Neumarkter Str. 61 D-81673 München		1.10.2008

— **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
26.9.2008	Exubera	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/05/327/001-018	30.9.2008

— **Issuing of a marketing authorization (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 authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
9.9.2008	Trocoxil	Mavacoxib	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	EU/2/08/084/001-005	Chewable tablets	QM01AH92	11.9.2008

— **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
2.9.2008	Advocate	Bayer Animal Health GmbH D-51368 Leverkusen	EU/2/03/039/001-030	4.9.2008
		Bayer HealthCare AG D-51368 Leverkusen		4.9.2008
5.9.2008	Profender	Bayer Animal Health GmbH D-51368 Leverkusen	EU/2/05/054/001-031	9.9.2008
		Bayer HealthCare AG D-51368 Leverkusen		9.9.2008
15.9.2008	Oxyglobin	Biopure Netherlands B.V. Parnassustoren Locatellikade 1 1076 AZ Amsterdam Nederland	EU/2/99/015/002	17.9.2008
19.9.2008	DRAXXIN	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/2/03/041/001-005	23.9.2008
26.9.2008	PRAC-TIC	Novartis Sanidad Animal S.L. Calle de la Marina, 206 E-Barcelona 08013	EU/2/06/066/001-012	30.9.2008

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004): 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
26.9.2008	Porcilis Pesti	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Nederland	EU/2/99/016/001-006	30.9.2008

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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