

**Summary of Community decisions on marketing authorizations in respect of medicinal products  
from 1 May 2007 to 31 May 2007**

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

(2007/C 144/06)

**— 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
2.5.2007	Focetria	A/Viet Nam/1194/2004 (H5N1) virus surface inactivated antigen	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1 I-53100 Siena	EU/1/07/385/001-004	Suspension for injection	J07BB02	4.5.2007
21.5.2007	ORENCIA	abatacept	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH United Kingdom	EU/1/07/389/001-003	Powder for concentrate for solution for infusion	L04AA24	23.5.2007
24.5.2007	Altargo	retapamulin	Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/07/390/001-004	Ointment	D06AX13	29.5.2007

<sup>(1)</sup> 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
22.5.2007	Mycograb	NeuTec Pharma plc Central Manchester & Manchester Children's Hospital NHS Trust Oxford Rd Manchester M13 9WL United Kingdom	—	29.5.2007

— **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
2.5.2007	Aranesp	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/01/185/001-073	4.5.2007
2.5.2007	Liprolog	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/01/195/001-015	4.5.2007
2.5.2007	BeneFIX	Wyeth Europa Ltd. Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/97/047/001-003	4.5.2007
2.5.2007	Vfend	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	EU/1/02/212/001-026	4.5.2007
2.5.2007	Nespo	Dompé Biotec S.p.A. Via San Martino, 12 I-20122 Milano	EU/1/01/184/001-073	4.5.2007
2.5.2007	Invirase	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/96/026/001-002	4.5.2007
2.5.2007	Norvir	Abbott laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/96/016/001 EU/1/96/016/003-004	4.5.2007
2.5.2007	Viramune	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/97/055/001-003	4.5.2007
2.5.2007	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001	4.5.2007

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2.5.2007	Osigraft	Howmedica International S. de R.L. Division of Stryker Corporation Raheen Industrial Estate Raheen Limerick Ireland	EU/1/01/179/001	4.5.2007
2.5.2007	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/99/110/001-009	4.5.2007
2.5.2007	Stocrin	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/99/111/001-011	4.5.2007
3.5.2007	Protopy	Astellas Pharma GmbH Neumarkter Str. 61 D-81673 München	EU/1/02/202/001-006	7.5.2007
3.5.2007	Crixivan	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/96/024/001-005 EU/1/96/024/007-008 EU/1/96/024/010	8.5.2007
3.5.2007	Protopic	Astellas Pharma GmbH Neumarkter Str. 61 D-81673 München	EU/1/02/201/001-006	7.5.2007
3.5.2007	Infanrix Hexa	GlaxoSmithKline Biologicals s.a. rue de l'Institut 89 B-1330 Rixensart	EU/1/00/152/001-018	7.5.2007
3.5.2007	Infanrix Penta	GlaxoSmithKline Biologicals s.a. rue de l'Institut 89 B-1330 Rixensart	EU/1/00/153/001-010	7.5.2007
3.5.2007	Humalog	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/96/007/002 EU/1/96/007/004-006 EU/1/96/007/008 EU/1/96/007/010-011 EU/1/96/007/015-021 EU/1/96/007/023-030	7.5.2007
11.5.2007	Prialt	Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/04/302/001-004	15.5.2007
14.5.2007	PritorPlus	Bayer HealthCare AG D-51368 Leverkusen	EU/1/02/215/001-014	16.5.2007
14.5.2007	Hepsera	Gilead Sciences International Limited Granta Park Abington Cambridge CB1 6GT United Kingdom	EU/1/03/251/001-002	16.5.2007

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14.5.2007	Humira	Abbott laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/03/256/001-010	16.5.2007
14.5.2007	Trudexa	Abbott laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/03/257/001-010	16.5.2007
15.5.2007	Omnitrope	Sandoz GmbH Biochemiestraße 10 A-Kundl 6250	EU/1/06/332/001-006	18.5.2007
15.5.2007	Iscover	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/98/070/001a-006a EU/1/98/070/001b-006b	17.5.2007
15.5.2007	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 174, avenue de France F-75013 Paris	EU/1/98/069/001a-006a EU/1/98/069/001b-006b	21.5.2007
15.5.2007	Xagrid	Shire Pharmaceutical Contracts Ltd Hampshire International Business Park Chineham Basingstoke Hampshire RG24 8EP United Kingdom	EU/1/04/295/001	17.5.2007
22.5.2007	Thelin	Encysive (UK) Limited Alder Castle House 10 Noble Street London EC2V 7QJ United Kingdom	EU/1/06/353/001-005	25.5.2007
22.5.2007	Zavesca	Actelion Registration Ltd BSI Building 13th Floor 389 Chiswick High Road London W4 4AL United Kingdom	EU/1/02/238/001	25.5.2007
22.5.2007	Teslascan	GE Healthcare AS Nycoveien 1-2 P.O. Box 4220 Nydalen N-0401 Oslo	EU/1/97/040/001-002	25.5.2007
22.5.2007	Opatanol	Alcon Laboratories (UK) Ltd. Pentagon Park Boundary Way Hemel Hempstead Herts HP2 7UD United Kingdom	EU/1/02/217/001-002	24.5.2007
30.5.2007	Xolair	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/05/319/001-004	1.6.2007
30.5.2007	Caelyx	Schering Plough Europe rue de Stalle, 73 B-1180 Bruxelles Stallestraat, 73 B-1180 Brussel	EU/1/96/011/001-004	1.6.2007

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
30.5.2007	Ventavis	Bayer Schering Pharma AG Müllerstraße 170-178 D-13342 Berlin	EU/1/03/255/001-005	1.6.2007
30.5.2007	Remicade	Centocor B.V. Einsteinweg 101 2333 CB Leiden Nederland	EU/1/99/116/001-003	1.6.2007
30.5.2007	LeukoScan	Immunomedics GmbH Otto-Röhm-Straße 69 D-64293 Darmstadt	EU/1/97/032/001	1.6.2007
30.5.2007	Ziagen	Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/99/112/001-002	1.6.2007
30.5.2007	Kivexa	Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/04/298/001-002	1.6.2007
30.5.2007	AVANDIA	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/00/137/002-018	1.6.2007
30.5.2007	Viramune	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/97/055/001-003	1.6.2007
30.5.2007	Avaglim	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/06/349/001-010	1.6.2007
31.5.2007	Ketek	Aventis Pharma S.A. 20, avenue Raymond Aron F-92160 Antony	EU/1/01/191/001-005	4.6.2007
31.5.2007	Levviax	Aventis Pharma S.A. 20, avenue Raymond Aron F-92160 Antony	EU/1/01/192/001-005	5.6.2007

— Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted

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14.5.2007	Nobilis Influenza H7N1	Inactivated whole avian influenza virus antigen of H7N1 subtype (strain, A/CK/Italy/473/99), inducing an HI titre of $\geq 6,0 \log_2$ as tested according to the potency test.	Intervet International B.V.	EU/2/07/073/001-004	Emulsion for injection	QI01AA23	16.5.2007

— Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted

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15.5.2007	METACAM	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein	EU/2/97/004/007-008 EU/2/97/004/014-015 EU/2/97/004/027-028	18.5.2007

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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