

**Summary of Community decisions on marketing authorizations in respect of medicinal products
from 1 September 2007 to 30 September 2007**

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

(2007/C 251/09)

— 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
7.9.2007	Gliolan	5-aminolevulinic acid hydrochloride	Medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstraße 3 D-20354 Hamburg	EU/1/07/413/001-003	Powder for oral solution	L01XD04	12.9.2007
17.9.2007	Yondelis	Trabectedin	Pharma Mar, S.A. Avda. de los Reyes 1 Polígono Industrial La Mina E-28770 Colmenar Viejo (Madrid)	EU/1/07/417/001-002	Powder for concentrate for solution for infusion	L01CX01	20.9.2007
18.9.2007	CELSENTRI	Maraviroc	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	EU/1/07/418/001-010	Film — coated tablet	J05AX09	20.9.2007
20.9.2007	ECALTA	Anidulafungin	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	EU/1/07/416/001	Powder and solvent for concentrate for solution for infusion	JO2AX06	24.9.2007
20.9.2007	Cervarix	Human Papilloma Virus-16 and Human Papilloma Virus 18 L1 proteins	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89 B-1330 Rixensart	EU/1/07/419/001-009	Suspension for injection	J07BM02	24.9.2007
26.9.2007	Galvus	Vildagliptin	Novartis Europharm Limited Wimblehurst Road Orsham West Sussex RH12 5AB United Kingdom	EU/1/07/414/001-017	Tablet	A10BH02	28.9.2007

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

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27.9.2007	Zalasta	Olanzapine	KRKA, d.d. Novo mesto Šmarješka cesta 6 SLO-8501 Novo mesto	EU/1/07/415/001-031 EU/1/07/415/032-056	Tablet Orodispersible tablet	N05AH03	1.10.2007

— **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
3.9.2007	Arixtra	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/206/001-020	5.9.2007
3.9.2007	Quixidar	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/207/001-020	5.9.2007
3.9.2007	TRIZIVIR	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/00/156/002-003	5.9.2007
3.9.2007	Combivir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/98/058/001-002	5.9.2007
3.9.2007	Mabthera	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/98/067/001-002	6.9.2007
3.9.2007	Novoseven	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/96/006/001-003	6.9.2007
7.9.2007	RotaTeq	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/06/348/001-002	11.9.2007
7.9.2007	Evra	Janssen-Cilag International NV Turnhoutseweg, 30 B-2340 Beerse	EU/1/02/223/001-003	11.9.2007
7.9.2007	Zavesca	Actelion Registration Ltd BSI Building 13th Floor 389 Chiswick High Road London W4 4AL United Kingdom	EU/1/02/238/001	11.9.2007
7.9.2007	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89 B-1330 Rixensart	EU/1/02/224/001-005	11.9.2007
13.9.2007	Tamiflu	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/02/222/001-002	18.9.2007
13.9.2007	Telzir	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN United Kingdom	EU/1/04/282/001-002	18.9.2007

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17.9.2007	Cerezyme	Genzyme Europe B.V. Goimeer 10 1411 DD Naarden Nederland	EU/1/97/053/001-005	20.9.2007
17.9.2007	Exelon	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/98/066/019-026	20.9.2007
17.9.2007	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/97/051/001-012	20.9.2007
17.9.2007	Cialis	Lilly ICOS Limited St Bride's House 10 Salisbury Square London EC4Y 8EH United Kingdom	EU/1/02/237/001-008	28.9.2007
18.9.2007	Actraphane	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/229/001-033	20.9.2007
18.9.2007	Protaphane	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/234/001-017	20.9.2007
18.9.2007	Insulatard	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/233/001-015	20.9.2007
18.9.2007	Xyrem	UCB Pharma Ltd 208 Bath Road Slough Berkshire SL1 3WE United Kingdom	EU/1/05/312/001	20.9.2007
18.9.2007	TOVIAZ	Schwarz Pharma AG Alfred-Nobel Straße 10 D-40789 Monheim Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	EU/1/07/386/001-010	20.9.2007 20.9.2007
18.9.2007	Velosulin	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/232/001-003	20.9.2007
18.9.2007	Actrapid	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/230/001-017	20.9.2007
18.9.2007	Mixtard	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/231/001-037	20.9.2007

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19.9.2007	Omnitrope	Sandoz GmbH Biochemiestraße 10 A-6250 Kundl	EU/1/06/332/007-009	21.9.2007
19.9.2007	Tamiflu	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/02/222/003-004	21.9.2007
20.9.2007	Somavert	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/02/240/001-004	24.9.2007
25.9.2007	NeuroBloc	Solstice Neurosciences Ltd Fitzwilton House Wilton Place Dublin 2 Ireland Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/00/166/001-003	27.9.2007 27.9.2007
25.9.2007	Prometax	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/98/092/019-026	27.9.2007
25.9.2007	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/97/050/001-012	27.9.2007

— **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
3.9.2007	Oxyblobin	Biopure Netherlands B.V. Parnassustoren Locatellikade 1 1076 AZ Amsterdam Nederland	EU/2/99/015/001	5.9.2007
4.9.2007	Econor	Novartis Animal Health Austria GmbH Biochemiestraße 10 A-6250 Kundl	EU/2/98/010/004-006 EU/2/98/010/017-018 EU/2/98/010/021-024	6.9.2007
7.9.2007	Cortavance	VIRBAC S.A. 1 ^{ère} Avenue 2065 m L.I.D. F-06516 Carros	EU/2/06/069/001	11.9.2007

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7.9.2007	Meloxidyl	CEVA SANTE ANIMALE Z.I. la Ballastière F-33500 Libourne	EU/2/06/070/001-003	11.9.2007
25.9.2007	Nobivac Bb	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Nederland	EU/2/02/034/001	27.9.2007

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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