Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 February 2006 to 28 February 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 78/03)

— 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
15.2.2006	Neupro	Rotigotine	Schwarz Pharma Ltd Shannon Industrial Estate Co.Clare Ireland	EU/1/05/331/001-013	Transdermal patch	N04BC09	17.2.2006
21.2.2006	Rotarix	Rotavirus vaccine, live	GlaxoSmithKline Biologicals SA rue de l'Institut 89 B-1330 Rixensart	EU/1/05/330/001-004	Powder and solvent for oral suspension	J07BH01	23.2.2006

([1]) OJ L 136 of 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
2.2.2006	Fareston	Orion Corporation Orionintie 1 FIN-02200 Espoo	EU/1/96/004/001-002	6.2.2006
9.2.2006	NovoSeven	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/96/006/001-003	13.2.2006
9.2.2006	Aerius	Schering Plough Europe Rue de Stalle, 73, Stallestraat, 73 B-1180 Brussel/Bruxelles	EU/1/00/160/001-034	13.2.2006
9.2.2006	Neoclarityn	Schering Plough Europe Rue de Stalle, 73, Stallestraat, 73 B-1180 Brussel/Bruxelles	EU/1/00/161/001-034	13.2.2006
9.2.2006	Azomyr	Schering Plough Europe Rue de Stalle, 73, Stallestraat, 73 B-1180 Brussel/Bruxelles	EU/1/00/157/001-034	13.2.2006
9.2.2006	Humalog	Eli Lilly Nederland BV 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/1/96/007/023-028	13.2.2006
9.2.2006	Xeloda	Roche Registration Limited 40 Broadwater Road Welwyn Garden City Hertfordshire AL7 3AY United Kingdom	EU/1/00/163/001-002	13.2.2006
9.2.2006	Replagal	TKT Europe AB Rinkebyvägen 11B S-182 36 Danderyd	EU/1/01/189/001-006	13.2.2006
9.2.2006	Fasturtec	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/00/170/001-002	13.2.2006
9.2.2006	Kepivance	Amgen Europe BV Minervum 7061 4817 ZK Breda Nederland	EU/1/05/314/001	13.2.2006
13.2.2006	Metalyse	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/00/169/004-006	15.2.2006
13.2.2006	Fabrazyme	Genzyme Europe BV Gooimeer 10 Naarden 1411 DD Nederland	EU/1/01/188/001-006	15.2.2006
13.2.2006	Liprolog	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/01/195/001-015	15.2.2006

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
13.2.2006	InductOs	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/02/226/001	15.2.2006
13.2.2006	HBVAXPRO	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/01/183/020-029	16.2.2006
14.2.2006	Insuman	Aventis Pharma Deutschland GmbH Brueningstraße 50 D-65926 Frankfurt am Main	EU/1/97/030/030 EU/1/97/030/035 EU/1/97/030/040 EU/1/97/030/045 EU/1/97/030/050 EU/1/97/030/055-084	16.2.2006
14.2.2006	Tasmar	Valeant Pharmaceuticals Limited Cedarwood Chineham Business Park Crockford lane Basingstoke RG24 8WD United Kingdom	EU/1/97/044/001-008	16.2.2006
17.2.2006	Pritor	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/98/089/011-014 EU/1/98/089/017-019	21.2.2006
28.2.2006	Viracept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/97/054/001 EU/1/97/054/003-006	2.3.2006
28.2.2006	Parareg	Dompé Biotec SpA Via San Martino, 12 I-20122 Milano	EU/1/04/293/001-012	2.3.2006
28.2.2006	Truvada	Gilead Sciences International Limited Granta Park Abington Cambridge CB1 6GT United Kingdom	EU/1/04/305/001	2.3.2006
28.2.2006	TachoSil	Nycomed Austria GmbH St.-Peter-Straße 25 A-4020 Linz	EU/1/04/277/001-004	2.3.2006
28.2.2006	BeneFIX	Wyeth Europa Ltd. Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/97/047/001-003	2.3.2006
28.2.2006	Aranesp	Amgen Europe BV Minervum 7061 4817 ZK Breda Nederland	EU/1/01/185/001-056	2.3.2006

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
28.2.2006	Lysodren	Laboratoire HRA Pharma 19 rue Frédérick Lemaître F-75020 Paris	EU/1/04/273/001	6.3.2006
28.2.2006	Glivec	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/01/198/001-013	2.3.2006
28.2.2006	Xagrid	Shire Pharmaceutical Contracts Ltd Hampshire International Business Park Chineham Basingstoke Hampshire RG24 8EP United Kingdom	EU/1/04/295/001	2.3.2006
28.2.2006	Exelon	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/98/066/001-018	2.3.2006
28.2.2006	Viread	Gilead Sciences International Limited Cambridge CB1 6GT United Kingdom	EU/1/01/200/001	2.3.2006
28.2.2006	Telzir	Glaxo Group Ltd Greenford Road, Greenford Middlesex UB6 0NN United Kingdom	EU/1/04/282/001-002	2.3.2006
28.2.2006	Nespo	Dompé Biotec SpA Via San Martino, 12 I-20122 Milano	EU/1/01/184/001-056	2.3.2006
28.2.2006	Rapamune	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead, Berkshire SL6 0PH United Kingdom	EU/1/01/171/001-012	2.3.2006
28.2.2006	Mimpara	Amgen Europe BV Minervum 7061 4817 ZK Breda Nederland	EU/1/04/292/001-012	2.3.2006
28.2.2006	Remicade	Centocor BV Einsteinweg 101 2333 CB Leiden Nederland	EU/1/99/116/001-003	2.3.2006

— **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
2.2.2006	Theryttrex	MDS Nordion SA Zoning Industriel B-6220 Fleurus	EU/1/02/245/001	6.2.2006

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
2.2.2006	Daquiran	Dr. Karl Thomae GmbH Birkendorfferstr. 65 D-88397 Biberach/Riss	EU/1/97/052/001-006 EU/1/97/052/009-010	6.2.2006

— **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
2.2.2006	Aivlosin	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	EU/2/04/044/001-005	6.2.2006
3.2.2006	Econor	Novartis Animal Health Austria GmbH Biochemiestraße 10 A-6250 Kundl	EU/2/98/010/004-006 EU/2/98/010/017-018 EU/2/98/010/023-024	7.2.2006
8.2.2006	Porcilis AR-T DF	Intervet International BV Wim de Körverstraat 35 5831 AN Boxmeer Nederland	EU/2/00/026/001-004	10.2.2006
8.2.2006	Pirsue	PFIZER Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/2/00/027/001-003	10.2.2006
13.2.2006	ProteqFlu Te	Merial 29 Avenue Tony Garnier F-69007 Lyon	EU/2/03/038/005	16.2.2006
13.2.2006	Advasure	PFIZER Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/2/00/025/001-004	15.2.2006
13.2.2006	ProteqFlu	Merial 29 avenue Tony Garnier F-69007 Lyon	EU/2/03/037/005	16.2.2006
28.2.2006	Stronghold	PFIZER Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/2/99/014/001-012	2.3.2006

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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