

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

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

(2006/C 321/06)

— 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
20.11.2006	BYETTA	exenatide	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/06/362/001-004	Solution for injection	A10BX04	22.11.2006
20.11.2006	Sprycel	dasatinib	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/06/363/001-009	Film-coated tablet	L01XX	22.11.2006

— 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
7.11.2006	Exubera	PFIZER Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/05/327/001-018	9.11.2006
7.11.2006	Humira	Abbott Laboratories Ltd. Queenborough Kent ME11 5EL United Kingdom	EU/1/03/256/001-010	9.11.2006
7.11.2006	Trudexa	Abbott Laboratories Ltd. Queenborough Kent ME11 5EL United Kingdom	EU/1/03/257/001-010	9.11.2006
14.11.2006	Humalog	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/96/007/015-017 EU/1/96/007/026-028	16.11.2006
14.11.2006	Zevalin	Schering AG Müllerstrasse 170-178 D-13342 Berlin	EU/1/03/264/001	16.11.2006

(*) OJL 136, 30.4.2004, p. 1.

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20.11.2006	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	22.11.2006
20.11.2006	Hycamtin	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/96/027/001 EU/1/96/027/003-005	22.11.2006
20.11.2006	Yttriga	QSA Global GmbH Gieselweg 1 D-38110 Braunschweig	EU/1/05/322/001	22.11.2006
20.11.2006	Liprolog	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/01/195/005-007 EU/1/01/195/013-015	22.11.2006
20.11.2006	Protopic	Astellas Pharma GmbH Neumarkter Str. 61 D-81673 München	EU/1/02/201/001-006	22.11.2006
20.11.2006	Protopy	Astellas Pharma GmbH Neumarkter Str. 61 D-81673 München	EU/1/02/202/001-006	22.11.2006
20.11.2006	Norvir	Abbott laboratories Ltd Queenborough Kent ME11 5EL United-Kingdom	EU/1/96/016/001 EU/1/96/016/003	22.11.2006
22.11.2006	TRIZIVIR	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/00/156/002-003	24.11.2006
22.11.2006	Evista	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/98/073/001-004	24.11.2006
22.11.2006	Optruma	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/98/074/001-004	24.11.2006
22.11.2006	PEGASYS	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City, AL7 1TW United Kingdom	EU/1/02/221/01-010	24.11.2006
22.11.2006	Tarceva	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/05/311/001-003	24.11.2006

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22.11.2006	Invirase	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/96/026/001-002	24.11.2006
22.11.2006	Hycamtin	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/96/027/001 EU/1/96/027/003-005	24.11.2006
22.11.2006	Avandamet	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/03/258/001-022	24.11.2006
22.11.2006	AVANDIA	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/00/137/002-018	24.11.2006
24.11.2006	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/283/001-007	28.11.2006
24.11.2006	Avaglim	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/06/349/001-008	28.11.2006
24.11.2006	Stocrin	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/99/111/010-011	28.11.2006
24.11.2006	Pedea	Orphan Europe SARL Immeuble 'Le Guillaumet' F-92046 Paris-La-Défense	EU/1/04/284/001	28.11.2006
24.11.2006	Aptivus	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein	EU/1/05/315/001	28.11.2006
24.11.2006	Replagal	Shire Human Genetic Therapies AB Rinkebyvägen 11B S-182 36 Danderyd	EU/1/01/189/001-006	28.11.2006
24.11.2006	Levitra	Bayer AG D-51368 Leverkusen,	EU/1/03/248/001-012	28.11.2006
24.11.2006	Vivanza	Bayer AG D-51368 Leverkusen	EU/1/03/249/001-012	28.11.2006

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24.11.2006	Xeristar	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein	EU/1/04/297/001-008	28.11.2006
24.11.2006	Cymbalta	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/296/001-008	28.11.2006
28.11.2006	Ziagen	Glaxo Group Ltd, Greenford Middlesex UB6 0NN United Kingdom	EU/1/99/112/001-002	1.12.2006
28.11.2006	Glivec	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/01/198/001-013	1.12.2006
28.11.2006	Tysabri	Elan Pharma International Ltd. Monksland Athlone County Westmeath Ireland	EU/1/06/346/001	4.12.2006
28.11.2006	Ebixa	H. Lundbeck A/S, Ottiliavej 9 DK-2500 Valby	EU/1/02/219/001-015	1.12.2006
28.11.2006	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstr. 100-104 D-60318 Frankfurt/Main	EU/1/02/218/001-011	1.12.2006
28.11.2006	Kepivance	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/05/314/001	1.12.2006
28.11.2006	Nespo	Dompé Biotec S.p.A. Via San Martino 12 I-20122 Milano	EU/1/01/184/001-068	1.12.2006
28.11.2006	Kivexa	Glaxo Group Ltd Berkeley Avenue Greenford Middlesex UB6 0NN United Kingdom	EU/1/04/298/001-002	1.12.2006
28.11.2006	YENTREVE	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/280/001-008	1.12.2006
28.11.2006	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU United Kingdom	EU/1/04/276/001-036	1.12.2006

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29.11.2006	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead, Berkshire, SL6 0PH United Kingdom	EU/1/99/126/001-018	1.12.2006
29.11.2006	Aldara	Laboratoires 3M Santé Boulevard de l'Oise F-95029 Cergy Pontoise Cedex	EU/1/98/080/001	1.12.2006
29.11.2006	Foscan	Biolitec pharma Ltd United Drug House Magna Drive Dublin 24 Ireland	EU/1/01/197/001-002	1.12.2006
29.11.2006	Emselex	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/04/294/001-028	1.12.2006
29.11.2006	Aranesp	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/01/185/001-068	1.12.2006

— **Withdrawal of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

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
14.11.2006	Monotard	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/235/001-004	16.11.2006
14.11.2006	Ultratard	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/02/236/001-004	16.11.2006

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14.11.2006	Yarvitan	Mitratapide	Janssen Animal Health B.V.B.A. Turnhoutseweg, 30 B-2340 Beerse	EU/2/06/063/001-003	Oral solution	QA08AB90	16.11.2006

— **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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20.11.2006	Virbagen Omega	VIRBAC S.A. 1 ere Avenue 2065 m L.I.D. F-06 516 Carros	EU/2/01/030/001-004	22.11.2006

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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