Summary of Community decisions on marketing authorizations in respect of medicinal products from 15 January 2005 to 15 February 2005

(Published pursuant to Article 12 or Article 34 of Council Regulation (EEC) No 2309/93 ([1]))

(2005/C 49/02)

— Issuing of a marketing authorization (Article 12 of Council Regulation (EEC) No 2309/93) 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
2.2.2005	Fendrix	GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, B-1330 Rixensart	EU/1/04/299/001-003	4.2.2005

— Modification of a marketing authorization (Article 12 of Council Regulation (EEC) No 2309/93) 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
20.1.2005	Norvir	Abbott laboratories Ltd, Queenborough, Kent ME11 5EL, United Kingdom	EU/1/96/016//001 EU/1/96/016/003	24.1.2005
20.1.2005	Zerit	Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, Hounslow TW3 3JA — United Kingdom	EU/1/96/009/001-017	24.1.2005
20.1.2005	Avandamet	SmithKline Beecham plc, 980 Great West Road, Brentford, Middlesex, TW8 9GS — United Kingdom	EU/1/03/258/001-012	24.1.2005
20.1.2005	Zerit	Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, Hounslow TW3 3JA — United Kingdom	EU/1/96/009/001-017	24.1.2005
20.1.2005	Rapamune	Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/01/171/011-012	24.1.2005
25.1.2005	NeupoPeg	Dompé Biotec S.p.A., Via San Martino, 12, I-20122 Milano	EU/1/02/228/001-002	27.1.2005
25.1.2005	Neulasta	Amgen Europe B.V., Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227/001-002	27.1.2005
25.1.2005	IntronA	Schering Plough Europe, Rue de Stalle, 73, B-1180 Bruxelles	EU/1/99/127/001-044	28.1.2005

([1]) OJ L 214 of 24 August 1993, page 1.

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
25.1.2005	Viraferon	Schering Plough Europe, Rue de Stalle, 73, B-1180 Bruxelles	EU/1/99/128/001-037	28.1.2005
25.1.2005	Xigris	Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/02/225/001-002	27.1.2005
25.1.2005	Trudexa	Abbott Laboratories Ltd., Queenborough, Kent ME11 5EL, United Kingdom	EU/1/03/257/001-006	27.1.2005
25.1.2005	Arixtra	Glaxo Group Ltd, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/02/206/001-017	27.1.2005
25.1.2005	Travatan	Alcon Laboratories (UK) Ltd., Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/01/199/001-002	27.1.2005
25.1.2005	Quixidar	Glaxo Group Ltd, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/02/206/001-017	27.1.2005
25.1.2005	Humira	Abbott Laboratories Ltd., Queenborough, Kent ME11 5EL, United Kingdom	EU/1/03/256/001-006	27.1.2005
25.1.2005	Rebetol	Schering Plough Europe, Rue de Stalle, 73, B-1180 Bruxelles — Stallestraat, 73, B-1180 Brussel	EU/1/99/107/001-004	27.1.2005
25.1.2005	Rebetol	Schering Plough Europe, Rue de Stalle, 73, B-1180 Bruxelles — Stallestraat, 73, B–1180 Brussel	EU/1/99/107/004	27.1.2005
26.1.2005	Remicade	Centocor B.V., Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-003	28.1.2005
26.1.2005	Bextra	Pharmacia-Pfizer EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/02/239/001-030	1.2.2005
26.1.2005	Dynastat	Pharmacia Europe EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/02/209/001-008	1.2.2005
26.1.2005	Rayzon	Pharmacia Europe EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/02/210/001-008	1.2.2005
26.1.2005	Prevenar	Wyeth-Lederle Vaccines S.A., Rue du Bosquet, 15, B-1348 Louvain-La-Neuve.	EU/1/00/167/001-007	28.1.2005
26.1.2005	Valdyn	Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/02/244/001-024	31.1.2005

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
26.1.2005	Visudyne	Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom.	EU/1/00/140/001	31.1.2005
26.1.2005	Pegasys	Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, Hertfordshire AL7 3AY, United Kingdom	EU/1/02/221/001-008	31.1.2005
26.1.2005	Renagel	Genzyme Europe B.V., Gooimeer 10, Naarden 1411 DD, Nederland	EU/1/99/123/001-011	28.1.2005
31.1.2005	Tractocile	Ferring AB, Soldattorpsvägen 5 — Box 30 047, Limhamn S-20061	EU/1/99/124/001-002	2.2.2005
2.2.2005	NovoNorm	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd	EU/1/98/076/001-002, EU/1/98/076/004-009, EU/1/98/076/011-016 EU/1/98/076/018-021	4.2.2005
4.2.2005	Prandin	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd	EU/1/00/162/001-018	8.2.2005
9.2.2005	Zyprexa	Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/96/022/016-018	11.2.2005
9.2.2005	Zyprexa	Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/96/022/002, EU/1/96/022/004, EU/1/96/022/006, EU/1/96/022/008-012, EU/1/96/022/014 EU/1/96/022/016-022	11.2.2005
9.2.2005	Zyprexa Velotab	Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/99/125/001-008	11.2.2005
14.2.2005	Keppra	UCB S.A. — Allée de la recherche, 60, B-1070 Bruxelles — Researchdreef, 60, B-1070 Brussel	EU/1/00/146/001-029	16.2.2005
14.2.2005	Avonex	Biogen Idec Ltd, 5 Roxborough Way, Foundation Park, Maidenhead, Berkshire, SL6 3UD, United Kindgom Biogen Idec France, 'Le Capitole' 55, avenue des Champs Pierreux, F-92012 Nanterre Cedex.	EU/1/97/033/001-003	16.2.2005
14.2.2005	Helicobacter Test INFAI	INFAI, Institut für biomedizinische Analytic und NMR Imaging GmbH — Universitätsstrasse 142, D-44799 Bochum	EU/1/97/045/001-004	16.2.2005

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
15.2.2005	Karvea	Bristol-Myers Squibb Pharma EEIG — 141-149 Staines Road, Hounslow TW3 3JA — United Kingdom	EU/1/97/049/001-030	17.2.2005
15.2.2005	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC — 174 avenue de France, F-75013 Paris	EU/1/97/046/001-030	17.2.2005

— **Modification of a marketing authorization (Article 34 of Council Regulation (EEC) No 2309/93) 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
31.1.2005	IBAFLIN	Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/022/001a-001b, 002a - 002b, 003a-003b, 004a-004b EU/2/00/022/005-008,	2.2.2005
31.1.2005	METACAM	Boehringer Ingelheim Vetmedica GmbH, D-55216 Ingelheim am Rhein	EU/2/97/004/007-008	2.2.2005