

Title and reference

Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 September 2005 to 30 September 2005(Published pursuant to Article 12 or Article 34 of Council Regulation (EEC) No 2309/93)

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Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 September 2005 to 30 September 2005

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

(2005/C 268/02)

— **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
19.9.2005	Tarceva	Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK-Hertfordshire AL7 3AY	EU/1/05/311/001-003	21.9.2005

— **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
5.9.2005	Ventavis	Schering AG, Müllerstraße 170-178, DE-13342 Berlin	EU/1/03/255//001-003	8.9.2005
5.9.2005	Trazec	Novartis Europharm Limited, Wimbleshurst Road, Horsham, UK-West Sussex RH12 5AB	EU/1/01/175/001-021	8.9.2005
5.9.2005	Forsteo	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten	EU/1/03/247/001-002	7.9.2005

		RH12 5AB		
7.9.2005	DaTSCAN	GE Healthcare Limited, UK-Little Chalfont Bucks HP7 9NA	EU/1/00/135/001-002	9.9.2005
7.9.2005	Emtriva	Gilead Sciences International Limited, UK-Cambridge CB1 6GT	EU/1/03/261/001-003	9.9.2005
7.9.2005	KOGENATE Bayer	Bayer AG, DE-51368 Leverkusen	EU/1/00/143/001-006	9.9.2005
7.9.2005	Helixate NexGen	Bayer AG, DE-51368 Leverkusen	EU/1/00/144/001-003	9.9.2005
8.9.2005	Nespo	Dompé Biotec S.p.A., Via San Martino, 12, IT-20122 Milano	EU/1/01/184/001-056	13.9.2005
8.9.2005	Herceptin	Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK-Hertfordshire AL7 3AY	EU/1/00/145/001	13.9.2005
8.9.2005	Xagrid	Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, Basingstoke, UK-Hampshire RG24 8EP	EU/1/04/295/001	13.9.2005
8.9.2005	Kivexa	Glaxo Group Ltd, Berkeley Avenue, Greenford, UK-Middlesex UB6 0NN	EU/1/04/298/001-002	13.9.2005
8.9.2005	Ziagen	Glaxo Group Ltd, Greenford, UK-Middlesex UB6 0NN	EU/1/99/112/001-002	13.9.2005
8.9.2005	Aranesp	Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda	EU/1/01/185/001-056	13.9.2005
8.9.2005	Karvezide	Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UK-Uxbridge UD8 1DH	EU/1/98/085/001-020	13.9.2005
8.9.2005	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC, 174 avenue de France, FR-75013 Paris	EU/1/98/086/001-020	13.9.2005
8.9.2005	PegIntron	Schering Plough Europe, Rue de Stalle, 73, BE-1180 Bruxelles — Stallestraat, 73, BE-1180 Brussel	EU/1/00/131/001-050	13.9.2005
8.9.2005	ViraferonPeg	Schering Plough Europe, Rue de Stalle, 73, BE-1180 Bruxelles — Stallestraat, 73, BE-1180 Brussel	EU/1/00/132/001-050	13.9.2005
8.9.2005	Raptiva	Serono Europe Limited, 56, Marsh Wall, UK-London E14 9TP	EU/1/04/291/001-002	14.9.2005
8.9.2005	Pylobactell	Torbet Laboratories Limited, Unit 14D, Wendover Road, Rackheath Industrial Estate, Norwich, UK-Norfolk NR13 6LH	EU/1/98/064/001	13.9.2005
13.9.2005	Infanrix Hexa	GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, BE-1330 Rixensart	EU/1/00/152/001-018	14.9.2005

13.9.2005	Hepsera	Gilead Sciences International Limited, UK-Cambridge CB1 6GT	EU/1/03/251/001	15.9.2005
13.9.2005	Erbix	Merck KGaA, Frankfurter Straße 250, DE-64293 Darmstadt	EU/1/04/281/001	14.9.2005
13.9.2005	Dynepo	Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, Basingstoke, UK-Hampshire RG24 8EP Aventis Pharma S.A., 20 Avenue Raymond Aron, Antony Cedex FR-92165	EU/1/02/211/001-009	15.9.2005
13.9.2005	Infanrix Penta	GlaxoSmithKline Biologicals s.a., rue de l'Institut 89, BE-1330 Rixensart	EU/1/00/153/001-010	14.9.2005
13.9.2005	Mimpara	Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda	EU/1/04/292/001-012	14.9.2005
13.9.2005	Avandamet	SmithKline Beecham plc, 980 Great West Road, Brentford, UK-Middlesex TW8 9GS	EU/1/03/258/013-014	14.9.2005
13.9.2005	Karvea	Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, UK-Hounslow TW3 3JA	EU/1/97/049/001-030	15.9.2005
13.9.2005	Keppra	UCB S.A., Allée de la recherche, 60, BE-1070 Bruxelles — Researchdreef, 60, BE-1070 Brussel	EU/1/00/146/001-029	16.9.2005
13.9.2005	Keppra	UCB S.A., Allée de la recherche, 60, BE-1070 Bruxelles — Researchdreef, 60, BE-1070 Brussel	EU/1/00/146/001-027	16.9.2005
13.9.2005	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC, 174 avenue de France, FR-75013 Paris	EU/1/97/046/001-030	15.9.2005
15.9.2005	Hepsera	Gilead Sciences International Limited, UK-Cambridge CB1 6GT	EU/1/03/251/001	20.9.2005
15.9.2005	Cymbalta	Eli Lilly Nederland BV, Grootslag 1-5, NL-3991 RA Houten	EU/1/04/296/001-006	20.9.2005
15.9.2005	Ariclaim	Boehringer Ingelheim International GmbH, Binger Straße 173, DE-55216 Ingelheim am Rhein	EU/1/04/283/001-007	20.9.2005
15.9.2005	Yentreve	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten	EU/1/04/280/001-007	20.9.2005
15.9.2005	Xeristar	Boehringer Ingelheim International GmbH, Binger Straße 173, DE-55216 Ingelheim am Rhein	EU/1/04/297/001-006	20.9.2005
15.9.2005	Bonviva	Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK	EU/1/03/265/003-004	20.9.2005

		40 Broadwater Road, Welwyn Garden City, UK- Hertfordshire AL7 3AY		
15.9.2005	Myocet	Elan Pharma International Ltd., WIL House, Shannon Business Park, Shannon, IE- County Clare	EU/1/00/141/001	20.9.2005
15.9.2005	NovoMix	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd	EU/1/00/142/004-005 EU/1/00/142/009-010	20.9.2005
16.9.2005	REYATAZ	Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, UK-Hounslow TW3 3JA	EU/1/03/267/001-007	20.9.2005
19.9.2005	Ariclaim	Boehringer Ingelheim International GmbH, Binger Straße 173, DE-55216 Ingelheim am Rhein	EU/1/04/283/001-007	21.9.2005
19.9.2005	Arava	Aventis Pharma Deutschland GmbH, DE-65926 Frankfurt am Main	EU/1/99/118/001-010	21.9.2005
19.9.2005	Yentreve	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten	EU/1/04/280/001-007	21.9.2005
19.9.2005	Hexavac	Sanofi Pasteur MSD, SNC, 8, rue Jonas Salk, FR-69007 Lyon	EU/1/00/147/001-012	21.9.2005
22.9.2005	Iscover	Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UK-Uxbridge UD8 1DH	EU/1/98/070/001a — 001b EU/1/98/070/002a — 002b EU/1/98/070/003a — 003b EU/1/98/070/004a — 001b	26.9.2005
22.9.2005	Plavix	Sanofi Pharma Bristol- Myers Squibb SNC, 174 avenue de France, FR-75013 Paris	EU/1/98/069/001a — 001b EU/1/98/069/002a — 002b EU/1/98/069/003a — 003b EU/1/98/069/004a — 001b	26.9.2005
29.9.2005	Remicade	Centocor B.V., Einsteinweg 101, NL-2333 CB Leiden	EU/1/99/116/001-003	4.10.2005

— **Withdrawal of a marketing authorization (Article 12 of Council Regulation (EEC) No 2309/93)**

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
22.9.2005	CEA-Scan	Immunomedics GmbH, Otto-Röhm- Straße 69, DE-64293 Darmstadt	EU/1/96/023/001	27.9.2005

— **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
19.9.2005	Pirsue	PFIZER Ltd, Ramsgate Road, Sandwich, UK-Kent CT13 9NJ	EU/2/00/027/001-003	21.9.2005

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

The European Medicines Agency
7, Westferry Circus, Canary Wharf
UK-London E14 4HB

(¹) OJ L 214 of 24.8.1993, p. 1.

