

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)

OJ C 268, 28.10.2005, p. 2-6 (ES, CS, DA, DE, ET, EL, EN, FR, IT, LV, LT, HU, NL, PL, PT, SK, SL, FI, SV)

Languages, formats and link to OJ

| | BG | ES | CS | DA | DE | ET | EL | EN | FR | GA | HR | IT | LV | LT | HU | MT | NL | PL | PT | RO | SK | SL | FI | SV |
|------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| HTML | | | | | | | | | | | | | | | | | | | | | | | | |
| PDF | | | | | | | | | | | | | | | | | | | | | | | | |
| Official Journal | | | | | | | | | | | | | | | | | | | | | | | | |

Multilingual display

Language 1 Language 2 Language 3 Display

Text

28.10.2005

Official Journal of the European Union

C 268/2

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.

