

Bendrijos sprendimų dėl leidimų prekiauti vaistais sąrašas nuo 2005 9 1 iki 2005 9 30(paskelbta sutinkamai su Tarybos Reglamentu (EEB) Nr. 2309/93 ⁽¹⁾ 12 arba 34 straipsniu

(2005/C 268/02)

— Leidimo prekiauti išdavimas (Tarybos Reglamentu (EEB) Nr. 2309/93 12 straipsnis): leidimas išduotas

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|--|------------------------------|----------------|
| 2005 9 19 | Tarceva | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK-Hertfordshire AL7 3AY | EU/1/05/311/001-003 | 2005 9 21 |

— Leidimo prekiauti pakeitimas (Tarybos Reglamentu (EEB) Nr. 2309/93 12 straipsnis): leidimas pakeistas

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|--|------------------------------|----------------|
| 2005 9 5 | Ventavis | Schering AG, Müllerstraße 170-178, DE-13342 Berlin | EU/1/03/255//001-003 | 2005 9 8 |
| 2005 9 5 | Trazec | Novartis Europharm Limited, Wimblehurst Road, Horsham, UK-West Sussex RH12 5AB | EU/1/01/175/001-021 | 2005 9 8 |
| 2005 9 5 | Forsteo | Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten | EU/1/03/247/001-002 | 2005 9 7 |
| 2005 9 5 | Starlix | Novartis Europharm Limited, Wimblehurst Road, Horsham, UK-West Sussex RH12 5AB | EU/1/01/174/001-021 | 2005 9 8 |
| 2005 9 7 | DaTSCAN | GE Healthcare Limited, UK-Little Chalfont Bucks HP7 9NA | EU/1/00/135/001-002 | 2005 9 9 |
| 2005 9 7 | Emtriva | Gilead Sciences International Limited, UK-Cambridge CB1 6GT | EU/1/03/261/001-003 | 2005 9 9 |
| 2005 9 7 | KOGENATE Bayer | Bayer AG, DE-51368 Leverkusen | EU/1/00/143/001-006 | 2005 9 9 |
| 2005 9 7 | Helixate NexGen | Bayer AG, DE-51368 Leverkusen | EU/1/00/144/001-003 | 2005 9 9 |
| 2005 9 8 | Nespo | Dompé Biotec S.p.A., Via San Martino, 12, IT-20122 Milano | EU/1/01/184/001-056 | 2005 9 13 |

⁽¹⁾ OL L 214, 1993 m. rugpjūčio 28 d., 1 puslapis.

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|---|------------------------------|----------------|
| 2005 9 8 | Herceptin | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK-Hertfordshire AL7 3AY | EU/1/00/145/001 | 2005 9 13 |
| 2005 9 8 | Xagrid | Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, Basingstoke, UK-Hampshire RG24 8EP | EU/1/04/295/001 | 2005 9 13 |
| 2005 9 8 | Kivexa | Glaxo Group Ltd, Berkeley Avenue, Greenford, UK-Middlesex UB6 0NN | EU/1/04/298/001-002 | 2005 9 13 |
| 2005 9 8 | Ziagen | Glaxo Group Ltd, Greenford, UK-Middlesex UB6 0NN | EU/1/99/112/001-002 | 2005 9 13 |
| 2005 9 8 | Aranesp | Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda | EU/1/01/185/001-056 | 2005 9 13 |
| 2005 9 8 | Karvezide | Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UK-Uxbridge UD8 1DH | EU/1/98/085/001-020 | 2005 9 13 |
| 2005 9 8 | CoAprovel | Sanofi Pharma Bristol-Myers Squibb SNC, 174 avenue de France, FR-75013 Paris | EU/1/98/086/001-020 | 2005 9 13 |
| 2005 9 8 | PegIntron | Schering Plough Europe, Rue de Stalle, 73, BE-1180 Bruxelles — Stallestraat, 73, BE-1180 Brussel | EU/1/00/131/001-050 | 2005 9 13 |
| 2005 9 8 | ViraferonPeg | Schering Plough Europe, Rue de Stalle, 73, BE-1180 Bruxelles — Stallestraat, 73, BE-1180 Brussel | EU/1/00/132/001-050 | 2005 9 13 |
| 2005 9 8 | Raptiva | Serono Europe Limited, 56, Marsh Wall, UK-London E14 9TP | EU/1/04/291/001-002 | 2005 9 14 |
| 2005 9 8 | Pylobactell | Torbet Laboratories Limited, Unit 14D, Wendover Road, Rackheath Industrial Estate, Norwich, UK-Norfolk NR13 6LH | EU/1/98/064/001 | 2005 9 13 |
| 2005 9 13 | Infanrix Hexa | GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, BE-1330 Rixensart | EU/1/00/152/001-018 | 2005 9 14 |

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|---|------------------------------|----------------|
| 2005 9 13 | Somavert | Pfizer Limited, Sandwich, UK-Kent, CT13 9NJ | EU/1/02/240/001-004 | 2005 9 14 |
| 2005 9 13 | Hepsera | Gilead Sciences International Limited, UK-Cambridge CB1 6GT | EU/1/03/251/001 | 2005 9 15 |
| 2005 9 13 | Erbix | Merck KGaA, Frankfurter Straße 250, DE-64293 Darmstadt | EU/1/04/281/001 | 2005 9 14 |
| 2005 9 13 | 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 | 2005 9 15 |
| 2005 9 13 | Infanrix Penta | GlaxoSmithKline Biologicals s.a., rue de l'Institut 89, BE-1330 Rixensart | EU/1/00/153/001-010 | 2005 9 14 |
| 2005 9 13 | Mimpara | Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda | EU/1/04/292/001-012 | 2005 9 14 |
| 2005 9 13 | Avandamet | SmithKline Beecham plc, 980 Great West Road, Brentford, UK-Middlesex TW8 9GS | EU/1/03/258/013-014 | 2005 9 14 |
| 2005 9 13 | Karvea | Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, UK-Hounslow TW3 3JA | EU/1/97/049/001-030 | 2005 9 15 |
| 2005 9 13 | Keppra | UCB S.A., Allée de la recherche, 60, BE-1070 Bruxelles — Researchdreef, 60, BE-1070 Brussel | EU/1/00/146/001-029 | 2005 9 16 |
| 2005 9 13 | Keppra | UCB S.A., Allée de la recherche, 60, BE-1070 Bruxelles — Researchdreef, 60, BE-1070 Brussel | EU/1/00/146/001-027 | 2005 9 16 |
| 2005 9 13 | Aprovel | Sanofi Pharma Bristol-Myers Squibb SNC, 174 avenue de France, FR-75013 Paris | EU/1/97/046/001-030 | 2005 9 15 |
| 2005 9 15 | Hepsera | Gilead Sciences International Limited, UK-Cambridge CB1 6GT | EU/1/03/251/001 | 2005 9 20 |
| 2005 9 15 | Cymbalta | Eli Lilly Nederland BV, Grootslag 1-5, NL-3991 RA Houten | EU/1/04/296/001-006 | 2005 9 20 |

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|---|--|----------------|
| 2005 9 15 | Ariclaim | Boehringer Ingelheim International GmbH, Binger Straße 173, DE-55216 Ingelheim am Rhein | EU/1/04/283/001-007 | 2005 9 20 |
| 2005 9 15 | Yentreve | Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten | EU/1/04/280/001-007 | 2005 9 20 |
| 2005 9 15 | Xeristar | Boehringer Ingelheim International GmbH, Binger Straße 173, DE-55216 Ingelheim am Rhein | EU/1/04/297/001-006 | 2005 9 20 |
| 2005 9 15 | Bonviva | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK-Hertfordshire AL7 3AY | EU/1/03/265/003-004 | 2005 9 20 |
| 2005 9 15 | Bondenza | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, UK-Hertfordshire AL7 3AY | EU/1/03/266/003-004 | 2005 9 20 |
| 2005 9 15 | Myocet | Elan Pharma International Ltd., WIL House, Shannon Business Park, Shannon, IE-County Clare | EU/1/00/141/001 | 2005 9 20 |
| 2005 9 15 | NovoMix | Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd | EU/1/00/142/004-005 EU/1/00/142/009-010 | 2005 9 20 |
| 2005 9 16 | REYATAZ | Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, UK-Hounslow TW3 3JA | EU/1/03/267/001-007 | 2005 9 20 |
| 2005 9 19 | Ariclaim | Boehringer Ingelheim International GmbH, Binger Straße 173, DE-55216 Ingelheim am Rhein | EU/1/04/283/001-007 | 2005 9 21 |
| 2005 9 19 | Arava | Aventis Pharma Deutschland GmbH, DE-65926 Frankfurt am Main | EU/1/99/118/001-010 | 2005 9 21 |
| 2005 9 19 | Yentreve | Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten | EU/1/04/280/001-007 | 2005 9 21 |
| 2005 9 19 | Hexavac | Sanofi Pasteur MSD, SNC, 8, rue Jonas Salk, FR-69007 Lyon | EU/1/00/147/001-012 | 2005 9 21 |
| 2005 9 22 | 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 | 2005 9 26 |

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|--|--|----------------|
| 2005 9 22 | 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 | 2005 9 26 |
| 2005 9 29 | Remicade | Centocor B.V., Einsteinweg 101, NL-2333 CB Leiden | EU/1/99/116/001-003 | 2005 10 4 |

— **Leidimo prekiauti panaikinimas (Tarybos Reglamento (EEB) Nr. 2309/93 12 straipsnis)**

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|--|------------------------------|----------------|
| 2005 9 22 | CEA-Scan | Immunomedics GmbH, Otto-Röhm-Straße 69, DE-64293 Darmstadt | EU/1/96/023/001 | 2005 9 27 |

— **Leidimo prekiauti pakeitimas (Tarybos Reglamento (EEB) Nr. 2309/93 34 straipsnis): leidimas pakeistas**

| Sprendimo data | Vaisto pavadinimas | Leidimo savininkas | Įrašo Bendrijos registre nr. | Pranešimo data |
|----------------|--------------------|---|------------------------------|----------------|
| 2005 9 19 | Pirsue | PFIZER Ltd, Ramsgate Road, Sandwich, UK-Kent CT13 9NJ | EU/2/00/027/001-003 | 2005 9 21 |

Pageidaujantys susipažinti su konkretaus vaisto viešo įvertinimo ataskaita ir su sprendimu dėl jo gali kreiptis į Europos vaistų vertinimo agentūrą:

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