

**Oversigt over fællesskabsbeslutninger om tilladelse til markedsføring af lægemidler fra 15. november 2004 til 15. december 2004**

*(Offentliggørelse i medfør af artikel 12 eller artikel 34 i Rådets forordning (EØF) nr. 2309/93 <sup>(1)</sup>)*

(2004/C 320/13)

— Udstedelse af markedsføringstilladelse (artikel 12 i forordning (EØF) nr. 2309/93): godkendt

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                                               | Nr. i EF-registret | Dato for notifikation |
|-----------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------------|
| 16.11.2004            | Xagrid           | Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, Basingstoke, Hampshire RG24 8EP, United Kingdom | EU/1/04/295/001    | 18.11.2004            |

— Ændring af markedsføringstilladelse (artikel 12 i forordning (EØF) nr. 2309/93): godkendt

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                        | Nr. i EF-registret                 | Dato for notifikation |
|-----------------------|------------------|---------------------------------------------------------------------------------------------------------------|------------------------------------|-----------------------|
| 16.11.2004            | Tamiflu          | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, Hertfordshire, AL7 3AY, United Kingdom    | EU/1/02/222/001                    | 18.11.2004            |
| 17.11.2004            | Trizivir         | Glaxo Group Ltd, Greenford, Middlesex, UB6 0NN, United Kingdom                                                | EU/1/00/156/001-003                | 19.11.2004            |
| 17.11.2004            | Targretin        | Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex, RH10 1BB, United Kingdom | EU/1/01/178/001                    | 19.11.2004            |
| 25.11.2004            | Bextra           | Pharmacia-Pfizer EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom                                               | EU/1/02/239/001-024                | 29.11.2004            |
| 25.11.2004            | ReFacto          | Wyeth Europa Ltd, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom              | EU/1/99/103/001-004                | 29.11.2004            |
| 30.11.2004            | Xigris           | Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, Nederland                                              | EU/1/02/225/001-002                | 2.12.2004             |
| 30.11.2004            | Tracleer         | Actelion Registration Ltd, BSI Building, 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom    | EU/1/02/220/001-005                | 2.12.2004             |
| 30.11.2004            | Cialis           | Lilly ICOS Limited, St Bride's House, 10 Salisbury Square, London, EC4Y 8EH, United Kingdom                   | EU/1/02/237/001<br>EU/1/02/237/005 | 2.12.2004             |
| 1.12.2004             | Micardis         | Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein                       | EU/1/98/090/001-014                | 3.12.2004             |

<sup>(1)</sup> EFT L 214 af 24.8.1993, s. 1.

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                                                                                         | Nr. i EF-registret  | Dato for notifikation |
|-----------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------|
| 6.12.2004             | Integrilin       | Glaxo Group Ltd, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom<br>Schering Plough Europe, Rue de Stalle 73, B-1180 Bruxelles, Stallestraat 73, B-1180 Brussel | EU/1/99/109/001-002 | 8.12.2004             |
| 6.12.2004             | Epivir           | Glaxo Group Ltd, Greenford Road, Greenford, Middlesex, UB6 0NN, United Kingdom                                                                                                 | EU/1/96/015/001-005 | 8.12.2004             |
| 6.12.2004             | Dynastat         | Pharmacia Europe EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom                                                                                                                | EU/1/02/209/001-008 | 8.12.2004             |
| 6.12.2004             | Sustiva          | Bristol-Myers Squibb Pharma EEIG, 141-149 Staines Road, Hounslow, TW3 3JA, United Kingdom                                                                                      | EU/1/99/110/001-009 | 8.12.2004             |
| 6.12.2004             | NutropinAq       | IPSEN Limited, 190 Bath Road, Slough, Berkshire, SL1 3XE, United Kingdom                                                                                                       | EU/1/00/164/001-005 | 8.12.2004             |
| 6.12.2004             | Strocrin         | Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, United Kingdom                                                                                     | EU/1/99/111/001-009 | 8.12.2004             |
| 6.12.2004             | Dynastat         | Pharmacia Europe EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom                                                                                                                | EU/1/02/209/001-008 | 8.12.2004             |
| 6.12.2004             | Panretin         | Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex, RH10 1BB, United Kingdom                                                                  | EU/1/00/149/001     | 8.12.2004             |
| 6.12.2004             | Arava            | Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main                                                                                                                     | EU/1/99/118/001-010 | 8.12.2004             |
| 6.12.2004             | Viread           | Gilead Sciences International Limited, Cambridge, CB1 6GT United Kingdom                                                                                                       | EU/1/01/200/001     | 8.12.2004             |
| 6.12.2004             | Rayzon           | Pharmacia Europe EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom                                                                                                                | EU/1/02/210/001-008 | 8.12.2004             |
| 6.12.2004             | Rayzon 6m        | Pharmacia Europe EEIG, Sandwich, Kent, CT13 9NJ, United Kingdom                                                                                                                | EU/1/02/210/001-008 | 8.12.2004             |
| 7.12.2004             | Kinzalmono       | Bayer AG, D-51368 Leverkusen                                                                                                                                                   | EU/1/98/091/001-014 | 9.12.2004             |
| 7.12.2004             | Micardis         | Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein                                                                                        | EU/1/98/090/001-014 | 10.12.2004            |
| 7.12.2004             | Pritor           | Glaxo Group Ltd, Greenford, Middlesex, UB6 0NN, United Kingdom                                                                                                                 | EU/1/98/089/001-016 | 9.12.2004             |

## — Tilbagetrækning af markedsføringstilladelse (artikel 12 i forordning (EØF) nr. 2309/93)

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                   | Nr. i EF-registret  | Dato for notifikation |
|-----------------------|------------------|------------------------------------------------------------------------------------------|---------------------|-----------------------|
| 8.12.2004             | Venvia           | SmithKline Beecham plc, New Horizons Court, Brentford, Middlesex, United Kingdom TW8 9EP | EU/1/00/138/001-012 | 10.12.2004            |
| 7.12.2004             | Nyracta          | SmithKline Beecham plc, New Horizons Court, Brentford, Middlesex, United Kingdom TW8 9EP | EU/1/00/139/001-012 | 9.12.2004             |

## — Ændring af markedsføringstilladelse (artikel 34 i forordning (EØF) nr. 2309/93): godkendt

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                        | Nr. i EF-registret  | Dato for notifikation |
|-----------------------|------------------|-------------------------------------------------------------------------------|---------------------|-----------------------|
| 25.11.2004            | Nobivac Bb       | Intervet International BV, Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/02/034/001     | 29.11.2004            |
| 25.11.2004            | Halocur          | Intervet International BV, Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/99/013/001-002 | 29.11.2004            |
| 7.12.2004             | Stronghold       | Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom           | EU/2/99/014/001-012 | 10.12.2004            |
| 7.12.2004             | Oxyglobin        | Biopure Netherlands BV, Prinses Irenestraat 59, 1077 WV Amsterdam, Nederland  | EU/2/99/015/001     | 9.12.2004             |