

Kokkuvõte ühenduse otsustest müügilubade kohta, mis käsitlevad ravimeid alates 15. aprill 2005 kuni 15. mai 2005

(Avaldatud vastavalt nõukogu määruse (EMÜ) nr 2309/93⁽¹⁾ artiklile 12 või artiklile 34)

(2005/C 130/04)

— **Müügiloa muutmise (nõukogu määruse (EMÜ) nr 2309/93 artikkel 12): Luba antud**

| Otsuse kuupäev | Ravimi nimetus | Müügiloa omanik | Kande number ühenduse registris | Teate kuupäev |
|----------------|----------------|--|---------------------------------|---------------|
| 20.4.2005 | Velcade | Janssen-Cilag International NV, Turnhoutseweg, 30 — B-2340 Beerse | EU/1/04/274/001 | 22.4.2005 |
| 20.4.2005 | Viramune | Boehringer Ingelheim International GmbH, Binger Strasse 173 — D-55216 Ingelheim am Rhein | EU/1/97/055/001-002 | 22.4.2005 |
| 20.4.2005 | Paxene | Norton Healthcare Limited, Albert Basin, Royal Docks, London E16 2QJ, United Kingdom | EU/1/99/113/001-004 | 22.4.2005 |
| 25.4.2005 | Zeffix | Glaxo Group Ltd, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/99/114/001-003 | 27.4.2005 |
| 25.4.2005 | HBVAXPRO | Sanofi Pasteur MSD, SNC, 8, rue Jonas Salk, F-69007 Lyon | EU/1/01/183/001-019 | 27.4.2005 |
| 25.4.2005 | Humira | Abbott Laboratories Ltd, Queenborough, Kent ME11 5EL, United Kingdom | EU/1/03/256/001-006 | 27.4.2005 |
| 25.4.2005 | GONAL f | Serono Europe Limited, 56, Marsh Wall, London E14 9TP, United Kingdom | EU/1/95/001/001-035 | 27.4.2005 |
| 25.4.2005 | Trudexa | Abbott Laboratories Ltd, Queenborough, Kent ME11 5EL, United Kingdom | EU/1/03/257/001-006 | 27.4.2005 |
| 27.4.2005 | Viagra | Pfizer Limited, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/98/077/001-012 | 29.4.2005 |
| 27.4.2005 | Keppra | UCB SA, Allée de la recherche, 60, B-1070 Bruxelles Researchdreef, 60, B-1070 Brussel | EU/1/00/146/001-027 | 29.4.2005 |
| 27.4.2005 | Lantus | Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main | EU/1/00/134/012 | 29.4.2005 |
| 27.4.2005 | Optisulin | Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main | EU/1/00/133/008 | 29.4.2005 |

(¹) EÜT L 214, 24.8.1993, lk 1

| Otsuse kuupäev | Ravimi nimetus | Müügiloo omanik | Kande number ühenduse registris | Teate kuupäev |
|----------------|----------------|---|---------------------------------|---------------|
| 27.4.2005 | Forsteo | Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/03/247/001-002 | 29.4.2005 |
| 27.4.2005 | Neupopeg | Dompé Biotec SpA, Via San Martino, 12, I-20122 Milano | EU/1/02/228/001-002 | 29.4.2005 |
| 27.4.2005 | Cellcept | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, Hertfordshire AL7 3AY, United Kingdom | EU/1/96/005/001-006 | 29.4.2005 |
| 27.4.2005 | Carbaglu | Orphan Europe, Immeuble "Le Guillaumet", F-92046 Paris La Défense | EU/1/02/246/001-003 | 29.4.2005 |
| 28.4.2005 | Herceptin | Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, Hertfordshire AL7 3AY, United Kingdom | EU/1/00/145/001 | 3.5.2005 |
| 28.4.2005 | Emend | Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/03/262/001-006 | 3.5.2005 |
| 28.4.2005 | Emend | Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/03/262/001-006 | 3.5.2005 |
| 28.4.2005 | Enbrel | Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/99/126/006-011 | 3.5.2005 |
| 28.4.2005 | Rapamune | Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/01/171/001-012 | 3.5.2005 |
| 29.4.2005 | Neulasta | Amgen Europe BV, Minervum 7061, 4817 ZK Breda, Nederland | EU/1/02/227/001-002 | 3.5.2005 |
| 10.5.2005 | Lyrica | Pfizer Ltd; Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom | EU/1/04/279/001-025 | 13.5.2005 |
| 10.5.2005 | Cancidas | Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/01/196/001-003 | 13.5.2005 |
| 13.5.2005 | Apidra | Aventis Pharma Deutschland GmbH, Brueningstraße 50, D-65926 Frankfurt am Main | EU/1/04/285/001-028 | 18.5.2005 |

— Müügiloa tagasivõtmine (nõukogu määruse (EMÜ) nr 2309/93 artikkel 12)

| Otsuse kuupäev | Ravimi nimetus | Müügiloa omanik | Kande number ühenduse registris | Teate kuupäev |
|----------------|----------------|--|---------------------------------|---------------|
| 25.4.2005 | Infanrix Hep B | GlaxoSmithKline Biologicals SA, rue de l'Institut 89, B-1330 Rixensart | EU/1/97/048/001-014 | 27.4.2005 |

— Müügiloa muutmise (nõukogu määruse (EMÜ) nr 2309/93 artikkel 34): Luba antud

| Otsuse kuupäev | Ravimi nimetus | Müügiloa omanik | Kande number ühenduse registris | Teate kuupäev |
|----------------|----------------|---|--|---------------|
| 18.4.2005 | Bayovac CSF E2 | Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom Bayer AG, Geschäftsbereich Tierge- sundheit, D-51368 Leverkusen | EU/2/00/025/001-004 | 20.4.2005 |
| 21.4.2005 | Eurifel FeLV | Merial, 29 Avenue Tony Garnier, F-69007 Lyon | EU/2/00/019/001-003 | 27.4.2005 |
| 27.4.2005 | Ibraxion | Merial, 29 avenue Tony Garnier, F-69007 Lyon | EU/2/99/017/001-006 | 29.4.2005 |
| 27.4.2005 | Metacam | Boehringer Ingelheim Vetmedica GmbH, D-55216 Ingelheim am Rhein | EU/2/97/004/001 EU/2/97/004/003-010 | 29.4.2005 |

Kõnealuseid ravimeid käsitleva avaliku hindamisaruande ja sellega seotud otsustega tutvumiseks tuleks võtta ühendust järgmise ametiga:

The European Medicines Agency
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Canary Wharf
UK — LONDON E14 4HB