IV

*(Oplysninger)*

# OPLYSNINGER FRA DEN EUROPÆISKE UNIONS INSTITUTIONER, ORGANER, KONTORER OG AGENTURER

# EUROPA-KOMMISSIONEN

## Oversigt over EU-afgørelser om tilladelse til markedsføring af lægemidler fra 1. januar 2011 til 28. februar 2011

*(Offentliggjort i henhold til artikel 13 eller artikel 38 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004* ([1]))

(2011/C 128/01)

([1]) EUT L 136 af 30.4.04, s. 1.

— **Udstedelse af markedsføringstilladelse (artikel 13 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004): Godkendt**

| Dato for afgørelser | Lægemidlets navn | INN-navn (International Non-Proprietary Name) | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Lægemiddelform | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|---|---|---|---|---|---|---|---|
| 6.1.2011 | Potactasol | topotecan | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland | EU/1/10/660/001-002 | Pulver til koncentrat til infusionsvæske, opløsning | L01XX17 | 10.1.2011 |
| 21.1.2011 | Docetaxel Teva Pharma | docetaxel | Teva Pharma B.V.<br>Computerweg 10, DR Utrecht 3542, Nederland | EU/1/10/662/001-002 | Koncentrat og solvens til infusionsvæske, opløsning | L01CD02 | 26.1.2011 |
| 21.1.2011 | Iasibon | Ibandronsyre | Pharmathen S.A.<br>6 Dervenakion, 15351 Pallini Attiki, Ελλάδα | EU/1/10/659/001-010 | Filmovertrukket tablet<br>Koncentrat till infusionsvaeske, opløsning | M05BA06 | 25.1.2011 |
| 27.1.2011 | Fluenz | influenzavaccine (levende svækket, nasal) | MedImmune, LLC<br>Lagelandseweg 78, 6545 CG Nijmegen, Nederland | EU/1/10/661/001-002 | Næsespray, suspension | J07BB03 | 1.2.2011 |
| 18.2.2011 | Entacapone Teva | entacapon | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/10/665/001-004 | Filmovertrukket tablet | N04BX02 | 22.2.2011 |
| 28.2.2011 | Daliresp | roflumilast | Nycomed GmbH<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland | EU/1/11/668/001-003 | Filmovertrukket tablet | R03DX07 | 2.3.2011 |
| 28.2.2011 | Esbriet | Pirfenidon | InterMune Europe Ltd<br>Wellesley House, Duke of Wellington Avenue, Royal Arsenal, London SE18 6SS, United Kingdom | EU/1/11/667/001-003 | Kapsler, hårde | L04AX05 | 2.3.2011 |
| 28.2.2011 | Lamivudine / Zidovudine Teva | Lamivudin/Zidovudin | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/10/663/001-002 | Filmovertrukket tablet | J05AR01 | 2.3.2011 |
| 28.2.2011 | Libertek | roflumilast | Nycomed GmbH<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland | EU/1/11/666/001-003 | Filmovertrukket tablet | R03DX07 | 2.3.2011 |
| 28.2.2011 | Xiapex | collagenase clostridium histolyticum | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom | EU/1/11/671/001 | Pulver og solvens til opløsning, injektion | M09AB02 | 2.3.2011 |

— **Ændring af markedsføringstilladelse (artikel 13 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004): Godkendt**

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 6.1.2011 | Invirase | Roche Registration Limited<br>6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/96/026/001-002 | 10.1.2011 |
| 6.1.2011 | Irbesartan HCT Winthrop | SANOFI PHARMA BRISTOL MYERS SQUIBB SNC<br>174 avenue de France, F- 75013 Paris, France | EU/1/06/377/001-028 | 11.1.2011 |
| 6.1.2011 | Irbesartan Winthrop | SANOFI PHARMA BRISTOL MYERS SQUIBB SNC<br>174 avenue de France, F- 75013 Paris, France | EU/1/06/376/001-033 | 11.1.2011 |
| 6.1.2011 | Lucentis | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/374/001 | 11.1.2011 |
| 6.1.2011 | Rapamune | Wyeth Europa Limited<br>Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/01/171/001<br>EU/1/01/171/007-010<br>EU/1/01/171/013-014 | 11.1.2011 |
| 6.1.2011 | Resolor | Movetis NV<br>Veedijk 58, B-2300 Turnhout, België | EU/1/09/581/001-008 | 11.1.2011 |
| 6.1.2011 | Tepadina | ADIENNE S.r.l.<br>via Broseta, 64/B, 24128 Bergamo, Italia | EU/1/10/622/001-002 | 11.1.2011 |
| 6.1.2011 | Yttriga | Eckert & Ziegler Nuclitec GmbH<br>Gieselweg 1, Braunschweig 38110, Deutschland | EU/1/05/322/001 | 10.1.2011 |
| 11.1.2011 | IntronA | Schering Plough Europe<br>Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België | EU/1/99/127/011-039<br>EU/1/99/127/041-044 | 18.1.2011 |
| 11.1.2011 | Pantoloc Control | Nycomed GmbH<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland | EU/1/09/519/001-004 | 13.1.2011 |
| 11.1.2011 | Rapiscan | Gilead Sciences International Limited<br>Cambridge CB21 6GT United Kingdom | EU/1/10/643/001 | 13.1.2010 |
| 13.1.2011 | Clopidogrel Winthrop | Sanofi-Aventis<br>174, avenue de France, F-75013 Paris, France | EU/1/08/465/001-020 | 17.1.2011 |
| 13.1.2011 | Copalia | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/372/037-039 | 17.1.2010 |
| 13.1.2011 | INOmax | INO Therapeutics AB<br>SE-181 81 Lidingö, Sverige | EU/1/01/194/001-002 | 18.1.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 13.1.2011 | Iscover | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/98/070/001a-001b<br>EU/1/98/070/002a-002b<br>EU/1/98/070/003a-003b<br>EU/1/98/070/004a-004b<br>EU/1/98/070/005a-005b<br>EU/1/98/070/006a-006b<br>EU/1/98/070/007a-007b<br>EU/1/98/070/008-010<br>EU/1/98/070/011a-011b<br>EU/1/98/070/012 | 17.1.2011 |
| 13.1.2011 | Nimvastid | KRKA, d.d., Novo mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/09/525/001-050 | 17.1.2011 |
| 13.1.2011 | Plavix | Sanofi Pharma Bristol-Myers Squibb SNC<br>174 avenue de France - 75013 Paris, France | EU/1/98/069/001a-001b<br>EU/1/98/069/002a-002b<br>EU/1/98/069/003a-003b<br>EU/1/98/069/004a-004b<br>EU/1/98/069/005a-005b<br>EU/1/98/069/006a-006b<br>EU/1/98/069/007a-007b<br>EU/1/98/069/008-010<br>EU/1/98/069/011a-011b<br>EU/1/98/069/012 | 17.1.2011 |
| 17.1.2011 | Cancidas | Merck Sharp & Dohme Ltd<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/01/196/001<br>EU/1/01/196/003 | 19.1.2011 |
| 17.1.2011 | Kuvan | Merck KGaA<br>Frankfurter Straße 250, 64293 Darmstadt, Deutschland | EU/1/08/481/001-003 | 19.1.2011 |
| 17.1.2011 | Nevanac | Alcon Laboratories (UK) Ltd.<br>Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom | EU/1/07/433/001 | 19.1.2011 |
| 21.1.2011 | Abilify | Otsuka Pharmaceutical Europe Ltd<br>Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1HU, United Kingdom | EU/1/04/276/001-020<br>EU/1/04/276/024-036 | 25.1.2011 |
| 21.1.2011 | Adenuric | Menarini International Operations Luxembourg S.A.<br>1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg | EU/1/08/447/001-004 | 25.1.2011 |
| 21.1.2011 | Arzerra | Glaxo Group Ltd<br>Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/10/625/001-002 | 26.1.2011 |
| 21.1.2011 | Cubicin | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/05/328/001-004 | 25.1.2011 |
| 21.1.2011 | Enbrel | Wyeth Europa Limited<br>Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/99/126/001-021 | 25.1.2011 |
| 21.1.2011 | Humira | Abbott Laboratories<br>Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE Maidenhead, Berks, United Kingdom | EU/1/03/256/001-010 | 25.1.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 21.1.2011 | INOmax | INO Therapeutics AB<br>SE-181 81 Lidingö, Sverige | EU/1/01/194/001-002 | 25.1.2011 |
| 21.1.2011 | Karvea | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/97/049/001-039 | 26.1.2011 |
| 21.1.2011 | Kuvan | Merck KGaA<br>Frankfurter Straße 250, 64293 Darmstadt, Deutschland | EU/1/08/481/001-003 | 25.1.2011 |
| 21.1.2011 | Mixtard | Novo Nordisk A/S<br>Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/02/231/001-023<br>EU/1/02/231/036-037 | 25.1.2011 |
| 21.1.2011 | Multaq | Sanofi-Aventis<br>174, avenue de France, F-75013 Paris, France | EU/1/09/591/001-004 | 25.1.2011 |
| 21.1.2011 | Olazax Disperzi | Glenmark Pharmaceuticals s.r.o.<br>City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika | EU/1/09/592/001-005 | 25.1.2011 |
| 21.1.2011 | Pandemrix | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/08/452/001 | 26.1.2011 |
| 21.1.2011 | Pradaxa | Boehringer Ingelheim International GmbH<br>Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/08/442/001-008 | 25.1.2011 |
| 21.1.2011 | Rapamune | Wyeth Europa Limited<br>Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/01/171/001<br>EU/1/01/171/007-010<br>EU/1/01/171/013-014 | 26.1.2011 |
| 21.1.2011 | Rasilez | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/405/001-040 | 25.1.2011 |
| 21.1.2011 | Revatio | Pfizer Limited<br>Sandwich, Kent, CT13 9NJ, United Kingdom | EU/1/05/318/002 | 25.1.2011 |
| 21.01.2011 | Revlimid | Celgene Europe Limited<br>Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom | EU/1/07/391/001-004 | 26.1.2011 |
| 21.1.2011 | RotaTeq | Sanofi Pasteur MSD, SNC<br>8, rue Jonas Salk, Lyon 69007, France | EU/1/06/348/001-002 | 26.1.2011 |
| 21.1.2011 | Sprimeo | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/407/001-020 | 26.1.2011 |
| 21.1.2011 | Temomedac | medac Gesellschaft für klinische Spezialpräparate mbH<br>Fehlandtstrasse 3, D-20354 Hamburg - Deutschland | EU/1/09/605/001-012 | 26.1.2011 |

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|---|---|---|---|---|
| 21.1.2011 | Thymanax | Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland | EU/1/08/498/001-008 | 25.1.2011 |
| 21.1.2011 | Valdoxan | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/08/499/001-008 | 26.1.2011 |
| 21.1.2011 | Yentreve | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/280/001-008 | 25.1.2011 |
| 24.1.2011 | Apidra | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/04/285/001-036 | 27.1.2011 |
| 24.1.2011 | Ceplene | EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland | EU/1/08/477/001 | 27.1.2011 |
| 24.1.2011 | Dafiro | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/371/001-039 | 27.1.2011 |
| 24.1.2011 | Eucreas | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/425/001-018 | 27.1.2011 |
| 24.1.2011 | Galvus | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/414/001-010 EU/1/07/414/018 | 27.1.2011 |
| 24.1.2011 | Isentress | Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/436/001-002 | 27.1.2011 |
| 24.1.2011 | Jalra | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/485/001-011 | 27.1.2011 |
| 24.01.2011 | Lantus | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/00/134/001-037 | 27.1.2011 |
| 24.1.2011 | NutropinAq | Ipsen Pharma 65, quai Georges Gorse, 92100 Boulogne-Billancourt, France | EU/1/00/164/003-005 | 27.1.2011 |
| 24.1.2011 | Olanzapine Glenmark | Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom | EU/1/09/587/001-017 | 27.1.2011 |
| 24.1.2011 | Olanzapine Glenmark Europe | Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom | EU/1/09/588/001-012 | 27.1.2011 |
| 24.1.2011 | Optisulin | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/00/133/001-032 | 27.1.2011 |

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|---|---|---|---|---|
| 24.1.2011 | Pelzont | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/460/009-011 EU/1/08/460/013-014 | 26.1.2011 |
| 24.1.2011 | Rotarix | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/05/330/001-011 | 27.1.2011 |
| 24.1.2011 | SonoVue | Bracco International B.V. Strawinskylaan 3051, 1077 ZX Amsterdam, Nederland | EU/1/01/177/002 | 27.1.2011 |
| 24.1.2011 | Synflorix | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique | EU/1/09/508/001-010 | 27.1.2011 |
| 24.1.2011 | Torisel | Wyeth Europa Ltd Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH, United Kingdom | EU/1/07/424/001 | 27.1.2011 |
| 24.1.2011 | Tredaptive | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/459/009-011 EU/1/08/459/013-014 | 26.1.2011 |
| 24.1.2011 | Trevaclyn | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/458/009-011 EU/1/08/458/013-014 | 26.1.2011 |
| 24.1.2011 | Vistide | Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom | EU/1/97/037/001 | 27.1.2011 |
| 24.1.2011 | Xarelto | Bayer Schering Pharma AG 13342 Berlin, Deutschland | EU/1/08/472/001-010 | 27.1.2011 |
| 24.1.2011 | Xiliarx | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/486/001-011 | 27.1.2011 |
| 26.1.2011 | Naglazyme | BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom | EU/1/05/324/001-002 | 27.1.2011 |
| 27.1.2011 | Adrovance | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/06/364/001-009 | 1.2.2011 |
| 27.1.2011 | Alimta | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/290/001-002 | 1.2.2011 |
| 27.1.2011 | Cymbalta | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/296/001-009 | 31.1.2011 |
| 27.1.2011 | Herceptin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/00/145/001 | 1.2.2011 |
| 27.1.2011 | Icandra | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/484/001-018 | 1.2.2011 |

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|---|---|---|---|---|
| 27.1.2011 | Menveo | Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia | EU/1/10/614/001 | 31.1.2011 |
| 27.1.2011 | Nonafact | Sanquin Plesmanlaan 125, Amsterdam 1066 CX, Nederland | EU/1/01/186/001-002 | 1.2.2011 |
| 27.1.2011 | Orgalutran | N.V. Organon P.O. Box 20, Kloosterstraat 6, 5340 BH Oss, Nederland | EU/1/00/130/001-002 | 31.1.2011 |
| 27.1.2011 | Ranexa | Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg | EU/1/08/462/001-012 | 1.2.2011 |
| 27.1.2011 | Rasilez HCT | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/491/001-080 | 1.2.2011 |
| 27.1.2011 | Regranex | Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België | EU/1/99/101/001 | 31.1.2011 |
| 27.1.2011 | Remicade | Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland | EU/1/99/116/001-005 | 1.2.2011 |
| 27.1.2011 | Ribavirin Mylan | Three Rivers Global Pharma Limited 20-22 Bedford Row, London WC1R4JS, United Kingdom | EU/1/10/634/001-004 | 23.2.2011 |
| 27.1.2011 | RotaTeq | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, Lyon 69007, France | EU/1/06/348/001-002 | 1.2.2011 |
| 27.1.2011 | Sebivo | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/388/001-003 | 1.2.2011 |
| 27.1.2011 | Simponi | Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland | EU/1/09/546/001-004 | 31.1.2011 |
| 27.1.2011 | Xeristar | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/297/001-008 | 1.2.2011 |
| 27.01.2011 | Zomarist | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/483/001-018 | 1.2.2011 |
| 1.2.2011 | Ariclaim | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/283/008-012 | 3.2.2011 |
| 1.2.2011 | Emend | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/03/262/001-008 | 3.2.2011 |
| 1.2.2011 | Exforge | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/370/001-039 | 3.2.2011 |

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|---|---|---|---|---|
| 1.2.2011 | Fosavance | Merck Sharp & Dohme Ltd<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/05/310/001-009 | 3.2.2011 |
| 1.2.2011 | Imprida | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/373/001-039 | 3.2.2011 |
| 1.2.2011 | INCRELEX | Ipsen Pharma<br>65, quai Georges Gorse, 92100 Boulogne-Billancourt, France | EU/1/07/402/001 | 3.2.2011 |
| 1.2.2011 | Insulin Human Winthrop | Sanofi-Aventis Deutschland GmbH<br>D-65926 Frankfurt am Main, Deutschland | EU/1/06/368/001-168 | 3.2.2011 |
| 1.2.2011 | Insuman | Sanofi-Aventis Deutschland GmbH<br>D-65926 Frankfurt am Main, Deutschland | EU/1/97/030/028-195 | 3.2.2011 |
| 1.2.2011 | Irbesartan Teva | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/576/001-039 | 3.2.2011 |
| 1.2.2011 | Nivestim | Hospira UK Limited<br>Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom | EU/1/10/631/001-009 | 3.2.2011 |
| 1.2.2011 | Orfadin | Swedish Orphan Biovitrum International AB<br>SE-112 76 Stockholm, Sweden | EU/1/04/303/001-003 | 3.2.2011 |
| 1.2.2011 | Riprazo | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/409/001-020 | 3.2.2011 |
| 1.2.2011 | Votrient | Glaxo Group Limited<br>Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/10/628/001-004 | 3.2.2011 |
| 2.2.2011 | Nplate | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/08/497/001-008 | 4.2.2011 |
| 2.2.2011 | Prevenar | Wyeth-Lederle Vaccines S.A.<br>Pleainlaan 17 Boulevard de la Plaine, 1050 Brussels - Bruxelles, Belgium | EU/1/00/167/001-008 | 4.2.2011 |
| 2.2.2011 | Prolia | Amgen Europe B.V.<br>Minervum 7061, NL-4817 ZK Breda, Nederland | EU/1/10/618/001-004 | 4.2.2011 |
| 2.2.2011 | Replagal | Shire Human Genetic Therapies AB<br>Svärdvägen 11D, 182 33 Danderyd, Sverige | EU/1/01/189/001-006 | 4.2.2011 |
| 2.2.2011 | Vantavo | Merck Sharp & Dohme Ltd.<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/09/572/001-009 | 4.2.2011 |
| 8.2.2011 | Biopoin | CT Arzneimittel GmbH<br>Lengeder Straße 42a, D-13407 Berlin, Deutschland | EU/1/09/565/001-028 | 10.2.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 8.2.2011 | Temodal | Schering Plough Europe<br>Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België | EU/1/98/096/001-025 | 14.2.2011 |
| 9.2.2011 | Cimzia | UCB Pharma SA.<br>Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België | EU/1/09/544/001-002 | 11.2.2011 |
| 9.2.2011 | Karvezide | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/98/085/001-034 | 11.2.2011 |
| 9.2.2011 | Olazax | Glenmark Pharmaceuticals s.r.o.<br>City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika | EU/1/09/597/001-005 | 11.2.2011 |
| 9.2.2011 | Peyona | CHIESI FARMACEUTICI SpA<br>Via Palermo 26/A, I-43100 Parma, ITALIA | EU/1/09/528/001-002 | 11.2.2011 |
| 9.2.2011 | Tesavel | Merck Sharp & Dohme Ltd<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/435/001-018 | 11.2.2011 |
| 9.2.2011 | Xelevia | Merck Sharp & Dohme Ltd<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/382/001-018 | 11.2.2011 |
| 11.2.2011 | Aprovel | Sanofi Pharma Bristol-Myers Squibb SNC<br>174 avenue de France - 75013 Paris, France | EU/1/97/046/001-039 | 15.2.2011 |
| 11.2.2011 | Azarga | Alcon Laboratories (UK) Ltd.<br>Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom | EU/1/08/482/001-002 | 15.2.2011 |
| 11.2.2011 | Brinavess | Merck Sharp & Dohme Limited<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/10/645/001-002 | 15.2.2011 |
| 11.2.2011 | Clopidogrel Krka | KRKA, d. d., Novo mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/09/556/001-011 | 15.2.2011 |
| 11.2.2011 | CoAprovel | Sanofi Pharma Bristol-Myers Squibb SNC<br>174 avenue de France - 75013 Paris, France | EU/1/98/086/001-034 | 15.2.2011 |
| 11.2.2011 | Crixivan | Merck Sharp & Dohme Ltd<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/96/024/001-005<br>EU/1/96/024/008<br>EU/1/96/024/010 | 15.2.2011 |
| 11.2.2011 | Eporatio | ratiopharm GmbH<br>Graf-Arco-Straße 3, D-89079 Ulm, Deutschland | EU/1/09/573/001-028 | 15.2.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 11.2.2011 | Januvia | Merck Sharp & Dohme Ltd<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/383/001-018 | 15.2.2011 |
| 11.2.2011 | Rilonacept Regeneron | Regeneron UK Limited<br>40 Bank Street, E14 5DS London, United Kingdom | EU/1/09/582/001 | 15.2.2011 |
| 11.2.2011 | Zutectra | Biotest Pharma GmbH<br>Landsteinerstr.5, 63303 Dreieich, Deutschland | EU/1/09/600/001 | 15.2.2011 |
| 11.2.2011 | Zyllt | KRKA, d.d., Novo mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/09/553/001-010 | 15.2.2011 |
| 18.2.2011 | Actrapid | Novo Nordisk A/S<br>Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/02/230/001-007<br>EU/1/02/230/016-017 | 22.2.2011 |
| 18.2.2011 | Elaprase | Shire Human Genetic Therapies AB<br>Svärdvägen 11D, 182 33 Danderyd, Sverige | EU/1/06/365/001-003 | 22.2.2011 |
| 18.2.2011 | Keppra | UCB Pharma SA.<br>Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België | EU/1/00/146/001-032 | 22.2.2011 |
| 18.2.2011 | Mimpara | Amgen Europe B.V.<br>Minervum 7061, NL-4817 ZK Breda, Nederland | EU/1/04/292/001-012 | 22.2.2011 |
| 18.2.2011 | Optaflu | Novartis Vaccines and Diagnostics GmbH<br>Emil-von-Behring-Strasse 76, D-35041 Marburg, Deutschland | EU/1/07/394/001-009 | 22.2.2011 |
| 18.2.2011 | Renagel | Genzyme Europe B.V.<br>Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/99/123/005-013 | 22.2.2011 |
| 21.2.2011 | Arzerra | Glaxo Group Ltd<br>Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/10/625/001-003 | 25.2.2011 |
| 21.2.2011 | Baraclude | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/06/343/001-007 | 28.2.2011 |
| 21.2.2011 | Cervarix | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, 1330 Rixensart, Belgique | EU/1/07/419/001-012 | 25.2.2011 |
| 21.2.2011 | Cialis | Eli Lilly Nederland B.V.<br>Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/02/237/001-009 | 23.2.2011 |
| 21.2.2011 | Clopidogrel Teva | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/540/001-016 | 24.2.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 21.2.2011 | Competact | Takeda Global Research and Development Centre (Europe) Ltd<br>61 Aldwych, London WC2B 4AE, United Kingdom | EU/1/06/354/001-011 | 23.2.2011 |
| 21.2.2011 | Conbriza | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/09/511/001-005 | 23.2.2011 |
| 21.2.2011 | Dukoral | Crucell Sweden AB<br>SE-105 21 Stockholm, Sweden | EU/1/03/263/001-003 | 1.3.2011 |
| 21.2.2011 | Dynastat | Pfizer Ltd<br>Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom | EU/1/02/209/001-008 | 23.2.2011 |
| 21.2.2011 | Efficib | Merck Sharp & Dohme Ltd.<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/457/001-016 | 24.2.2011 |
| 21.2.2011 | Enbrel | Wyeth Europa Limited<br>Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/99/126/001-021 | 25.2.2011 |
| 21.2.2011 | Firazyr | Jerini AG<br>Invalidenstr. 130, D-10115 Berlin, Deutschland | EU/1/08/461/001-002 | 24.2.2011 |
| 21.2.2011 | Glivec | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/01/198/001-013 | 28.2.2011 |
| 21.2.2011 | Humira | Abbott Laboratories Ltd<br>Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom | EU/1/03/256/001-010 | 23.2.2011 |
| 21.2.2011 | Insulatard | Novo Nordisk A/S<br>Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/02/233/005-007 | 25.2.2011 |
| 21.2.2011 | Intanza | Sanofi Pasteur MSD SNC<br>8, rue Jonas Salk, Lyon 69007, France | EU/1/08/505/001-006 | 23.2.2011 |
| 21.2.2011 | Ivemend | Merck Sharp & Dohme Limited<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/437/001-004 | 24.2.2011 |
| 21.2.2011 | Janumet | Merck Sharp & Dohme Ltd.<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/455/001-016 | 24.2.2011 |
| 21.2.2011 | Kineret | Swedish Orphan Biovitrum AB (publ)<br>SE-112 76, Stockholm, Sverige | EU/1/02/203/001-004 | 25.2.2011 |
| 21.2.2011 | Levemir | Novo Nordisk A/S<br>Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/04/278/001-003 | 28.2.2011 |
| 21.2.2011 | Myozyme | Genzyme Europe B.V.<br>Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/06/333/001-003 | 28.2.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 21.2.2011 | Neupro | Schwarz Pharma Ltd<br>Shannon, Industrial Estate, Co.Clare, Ireland | EU/1/05/331/001-055 | 25.2.2011 |
| 21.2.2011 | Pritor | Bayer Schering Pharma AG<br>13342 Berlin, Deutschland | EU/1/98/089/001-022 | 25.2.2011 |
| 21.2.2011 | PritorPlus | Bayer Schering Pharma AG<br>13342 Berlin, Deutschland | EU/1/02/215/001-021 | 28.2.2011 |
| 21.2.2011 | Protaphane | Novo Nordisk A/S<br>Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/02/234/005-007 | 25.2.2011 |
| 21.2.2011 | Protopic | Astellas Pharma Europe B.V.<br>Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland | EU/1/02/201/001-006 | 28.2.2011 |
| 21.2.2011 | Qutenza | Astellas Pharma Europe B.V.<br>Elisabethhof 19, 2353 EW Leiderdorp, Nederland | EU/1/09/524/001-002 | 25.2.2011 |
| 21.2.2011 | Ranexa | Menarini International Operations Luxembourg S.A.<br>1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg | EU/1/08/462/001-012 | 25.2.2011 |
| 21.2.2011 | Rasilez | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/405/001-040 | 25.2.2011 |
| 21.2.2011 | Rasilez HCT | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/491/001-080 | 25.2.2011 |
| 21.02.2011 | Remicade | Janssen Biologics B.V.<br>Einsteinweg 101, 2333 CB Leiden, Nederland | EU/1/99/116/001-005 | 25.2.2011 |
| 21.2.2011 | Ribavirin Teva | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/509/001-004 | 24.2.2011 |
| 21.2.2011 | Ribavirin Teva Pharma BV | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/527/001-016 | 24.2.2011 |
| 21.2.2011 | Riprazo | Novartis Europharm Limited<br>Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/409/001-020 | 28.2.2011 |
| 21.2.2011 | Ristaben | Merck Sharp & Dohme Ltd.<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/10/621/001-018 | 24.2.2011 |
| 21.2.2011 | Ristfor | Merck Sharp & Dohme Ltd.<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/10/620/001-016 | 24.2.2011 |
| 21.2.2011 | Simponi | Janssen Biologics B.V.<br>Einsteinweg 101, CB Leiden 2333, Nederland | EU/1/09/546/001-004 | 23.2.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 21.2.2011 | Sprimeo | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/407/001-020 | 28.3.2011 |
| 21.2.2011 | Stocrin | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/99/111/001-005 EU/1/99/111/008-011 | 25.2.2011 |
| 21.2.2011 | Tamiflu | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/02/222/001-004 | 23.2.2011 |
| 21.2.2011 | Tysabri | Elan Pharma International Ltd. Monksland, Athlone, County Westmeath, Ireland | EU/1/06/346/001 | 23.2.2011 |
| 21.2.2011 | Velmetia | Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/456/001-016 | 24.2.2011 |
| 21.2.2011 | Ventavis | Bayer Schering Pharma AG Müllerstrasse 170-178, D - 13342 Berlin, Deutschland | EU/1/03/255/001-008 | 23.2.2011 |
| 21.2.2011 | Volibris | Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/08/451/001-004 | 2.3.2011 |
| 21.2.2011 | Zylagren | KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/09/558/001-010 | 28.2.2011 |
| 21.2.2011 | Zyprexa | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/96/022/016-017 | 23.2.2011 |
| 28.2.2011 | Altargo | Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/07/390/001-004 | 4.3.2011 |
| 28.2.2011 | Aranesp | Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland | EU/1/01/185/001-022 EU/1/01/185/031-111 | 4.3.2011 |
| 28.2.2011 | Arixtra | Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/02/206/001-035 | 2.3.2011 |
| 28.2.2011 | Avastin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/04/300/001-002 | 4.3.2011 |
| 28.2.2011 | Baraclude | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/06/343/001-007 | 3.3.2011 |
| 28.2.2011 | Clopidogrel Qualimed | Qualimed 117, Allée des Parcs, 69 800 Saint Priest, France | EU/1/09/557/001-010 | 4.3.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 28.2.2011 | Clopidogrel TAD | TAD Pharma GmbH Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Deutschland | EU/1/09/555/001-009 | 4.3.2011 |
| 28.2.2011 | Fabrazyme | Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/01/188/001-006 | 4.3.2011 |
| 28.2.2011 | Firazyr | Jerini AG Invalidenstr. 130, D-10115 Berlin, Deutschland | EU/1/08/461/001-002 | 4.3.2011 |
| 28.2.2011 | IDflu | Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France | EU/1/08/507/001-006 | 3.3.2011 |
| 28.2.2011 | Ilaris | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/564/001-002 | 4.3.2011 |
| 28.2.2011 | Invanz | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/02/216/001-002 | 3.3.2011 |
| 28.2.2011 | Kaletra | Abbott Laboratories Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE Maidenhead, Berks, United Kingdom | EU/1/01/172/001-008 | 4.3.2011 |
| 28.2.2011 | Kinzalkomb | Bayer Schering Pharma AG D-13342 Berlin, Deutschland | EU/1/02/214/001-015 | 2.3.2011 |
| 28.2.2011 | Kinzalmono | Bayer Schering Pharma AG D-13342 Berlin, Deutschland | EU/1/98/091/001-014 | 2.3.2011 |
| 28.2.2011 | Micardis | Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland | EU/1/98/090/001-020 | 2.3.2011 |
| 28.2.2011 | MicardisPlus | Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland | EU/1/02/213/001-023 | 3.3.2011 |
| 28.2.2011 | NovoMix | Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/00/142/004-005 EU/1/00/142/009-025 | 3.3.2011 |
| 28.2.2011 | Omnitrope | Sandoz GmbH Biochemiestrasse 10, Kundl 6250, Österreich | EU/1/06/332/001-009 | 2.3.2011 |
| 28.2.2011 | Onglyza | Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom | EU/1/09/545/011-015 | 3.3.2011 |
| 28.2.2011 | Onglyza | Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom | EU/1/09/545/001-010 | 3.3.2011 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 28.2.2011 | Osigraft | Howmedica International S. de R.L. Division of Stryker Corporation, Raheen Industrial Estate, Raheen, Limerick, Ireland | EU/1/01/179/001 | 4.3.2011 |
| 28.2.2011 | Osseor | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/04/287/001-006 | 4.3.2011 |
| 28.2.2011 | PegIntron | Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België | EU/1/00/131/001-050 | 3.3.2011 |
| 28.2.2011 | PREZISTA | Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België | EU/1/06/380/001-005 | 4.3.2011 |
| 28.2.2011 | ProQuad | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France | EU/1/05/323/001-013 | 2.3.2011 |
| 28.2.2011 | Protelos | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/04/288/001-006 | 4.3.2011 |
| 28.2.2011 | Quadramet | CIS bio international Boite Postale 32 - F-91192 Gif-sur-Yvette - France | EU/1/97/057/001 | 4.4.2011 |
| 28.2.2011 | RotaTeq | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, Lyon 69007, France | EU/1/06/348/001-002 | 3.3.2011 |
| 28.2.2011 | Siklos | ADDMEDICA 101, rue Saint Lazare, Paris 75009, France | EU/1/07/397/001-004 | 3.3.2011 |
| 28.2.2011 | Tracleer | Actelion Registration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom | EU/1/02/220/001-006 | 3.3.2011 |
| 28.2.2011 | Vedrop | Orphan Europe SARL Immeuble Le Wilson - 70 Avenue du Général de Gaulle - F 92 800 Puteaux - France | EU/1/09/533/001-003 | 3.3.2011 |
| 28.2.2011 | Ytracis | CIS bio international Boite Postale 32 - F-91192 Gif-sur-Yvette Cedex- France | EU/1/03/250/001 | 4.3.2011 |

— **Tilbagekaldelse af markedsføringstilladelse (artikel 13 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004)**

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 6.1.2011 | Thelin | Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/06/353/001-005 | 11.1.2011 |
| 1.2.2011 | Clopidogrel 1A Pharma | Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland | EU/1/09/542/001-007 | 3.2.2011 |

— **Udstedelse af markedsføringstilladelse (artikel 38 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004** ([1])**: Godkendt**

| Dato for afgørelser | Lægemidlets navn | INN-navn (International Non-Proprietary Name) | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Lægemiddelform | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|---|---|---|---|---|---|---|---|
| 27.01.2011 | Hiprabovis IBR Marker Live | Levende gE<sup>-</sup> tk<sup>-</sup> dobbelt-gen deleteret bovin herpesvirus type 1 (BoHV-1), stamme CEDDEL | Laboratorios Hipra, S.A.<br>Avda. La Selva, 135, 17170- Amer (Girona), España | EU/2/10/114/001-002 | Lyofilisat til suspension | QI02AD01 | 1.2.2011 |
| 11.2.2011 | Comfortis | spinosad | Eli Lilly and Company Ltd<br>Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom | EU/2/10/115/001-010 | Tyggetabletter | QP53BX03 | 15.2.2011 |
| 18.2.2011 | Activyl | indoxacarb | Intervet International B.V.<br>Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/10/118/001-014 | Spot-on, opløsning | QP53AX27 | 22.2.2011 |
| 18.2.2011 | Cimalgex | Cimicoxib | Vétoquinol SA<br>Magny-Vernois - 70200 LURE - France | EU/2/10/119/001-012 | Tablet | QM01AH93 | 24.2.2011 |
| 18.2.2011 | Purevax Rabies | Rabies rekombinant canarypox virus (vCP65) | MERIAL<br>29 avenue Tony Garnier, 69007 LYON, France | EU/2/10/117/001-002 | Suspension til injektion | QI06AX | 22.2.2011 |
| 21.2.2011 | Melosus | Meloxicam | CP-Pharma Handelsgesellschaft mbH<br>Ostlandring 13, D-31303 Burgdorf, Deutschland | EU/2/10/116/001-004 | Oral suspension | QM01AC06 | 24.2.2011 |

([1]) EUT L 136 af 30.4.04, s. 1.

— **Ændring af markedsføringstilladelse (artikel 38 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004): Godkendt**

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 6.1.2011 | Econor | Novartis Animal Health Austria GmbH Biochemiestrasse 10, 6250 Kundl, Österreich | EU/2/98/010/004-006<br>EU/2/98/010/017-018<br>EU/2/98/010/021-025 | 11.1.2011 |
| 13.1.2011 | Duvaxyn WNV | Fort Dodge Animal Health Ltd Flanders Road, Hedge End, Southampton SO30 4QH, United Kingdom | EU/2/08/086/001-003 | 18.1.2011 |
| 13.1.2011 | Palladia | Pfizer Ltd Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/2/09/100/001-003 | 17.1.2011 |
| 17.1.2011 | Zolvix | Novartis Healthcare A/S Lyngbyvej 172, DK-2100 Copenhagen, Denmark | EU/2/09/101/001-010 | 19.1.2011 |
| 21.1.2011 | Dicural | Fort Dodge Animal Health Holland C.J. van Houtenlaan 36, 1381 CP Weesp, Nederland | EU/2/97/003/001-018 | 25.1.2011 |
| 21.1.2011 | Zulvac 8 Ovis | Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/2/09/104/001-002 | 26.1.2011 |
| 24.1.2011 | Poulvac FluFend H5N3 RG | Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom | EU/2/06/060/001-002 | 27.1.2011 |
| 24.1.2011 | Rheumocam | Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, IRELAND | EU/2/07/078/001-010 | 26.1.2011 |
| 27.1.2011 | Ingelvac CircoFLEX | Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland | EU/2/07/079/001-004 | 1.2.2011 |
| 27.1.2011 | Meloxidyl | CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France | EU/2/06/070/005-007 | 1.2.2011 |
| 11.2.2011 | SevoFlo | Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, UNITED KINGDOM | EU/2/02/035/007 | 15.2.2011 |

— **Suspension af markedsføringstilladelse (artikel 45 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004)**

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 24.1.2011 | Acticam | Ecuphar NV Legeweg 157-I, B-8020 Oostkamp, Belgïe | EU/2/08/088/001-003 | 26.1.2011 |

Alle interesserede kan ved henvendelse på nedenstående adresse få tilsendt den offentlige evalueringsrapport om de pågældende lægemidler og de afgørelser, der er truffet vedrørende disse:

The European Medicines Agency
7, Westferry Circus, Canary Wharf
UK - LONDON E14 4H