

**Oversigt over fællesskabsbeslutninger om tilladelse til markedsføring af lægemidler fra 1. december 2009 til 31. december 2009**

(Offentliggjort i henhold til artikel 13 eller artikel 38 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004 <sup>(1)</sup>)

(2010/C 22/04)

— Udstedelse af markedsføringstilladelse (artikel 13 i forordning (EF) nr. 726/2004): godkendt

| Dato for beslutningen | Lægemidlets navn           | INN-navn (internationale fællesnavn)                             | Indehaver af markedsføringstilladelsen                                                                                                 | Nummer i EF-registret | Lægemiddelform              | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|-----------------------|----------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------|-------------------------------------------------|-----------------------|
| 3.12.2009             | Olanzapine Glenmark Europe | Olanzapin                                                        | Glenmark Generics (Europe) Limited<br>Laxmi House<br>2-B Draycott Avenue<br>Kenton<br>Harrow<br>Middlesex<br>HA3 0BU<br>UNITED KINGDOM | EU/1/09/588/001-017   | Orodispergerende tablet     | N05AH03                                         | 7.12.2009             |
| 3.12.2009             | Olanzapine Glenmark        | Olanzapin                                                        | Glenmark Generics (Europe) Limited<br>Laxmi House<br>2-B Draycott Avenue<br>Kenton<br>Harrow<br>Middlesex<br>HA3 0BU<br>UNITED KINGDOM | EU/1/09/587/001-012   | Tablet                      | N05AH03                                         | 7.12.2009             |
| 9.12.2009             | Prevenar 13                | Konjugeret polysaccharid pneumokovaccine (13-valent, adsorberet) | Wyeth Lederle Vaccines S.A.<br>Rue du Bosquet 15<br>1348 Louvain-la-Neuve<br>BELGIQUE                                                  | EU/1/09/590/001-006   | Injektionsvæske, suspension | J07AL02                                         | 11.12.2009            |
| 10.12.2009            | Lamivudine Teva Pharma B.V | Lamivudin                                                        | Teva Pharma B.V.<br>Computerweg 10<br>3542 DR Utrecht<br>NEDERLAND                                                                     | EU/1/09/596/001-014   | Filmovertrukket tablet      | J05AF05                                         | 14.12.2009            |
| 10.12.2009            | Olazax Disperzi            | Olanzapin                                                        | Glenmark Pharmaceuticals s.r.o<br>City Tower<br>Hvězdova 1716/2b<br>140 78 Praha 4<br>ČESKÁ REPUBLIKA                                  | EU/1/09/592/001-005   | Orodispergerende tablet     | N05AH03                                         | 14.12.2009            |

<sup>(1)</sup> EUT L 136 af 30.4.2004, s. 1.

| Dato for beslutningen | Lægemidlets navn      | INN-navn (internationale fællesnavn) | Indehaver af markedsføringstilladelsen                                                                 | Nummer i EF-registret                      | Lægemiddelform                   | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|-----------------------|-----------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------|-------------------------------------------------|-----------------------|
| 10.12.2009            | Sildenafil Actavis    | sildenafil                           | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>ICELAND                        | EU/1/09/595/001-015                        | Filmovertrukket tablet           | G04BE03                                         | 14.12.2009            |
| 11.12.2009            | Olazax                | Olanzapin                            | Glenmark Pharmaceuticals s.r.o.<br>City Tower<br>Hvězdova 1716/2b<br>140 78 Praha 4<br>ČESKÁ REPUBLIKA | EU/1/09/597/001-005                        | Tablet                           | N05AH03                                         | 15.12.2009            |
| 11.12.2009            | Rivastigmine Hexal    | Rivastigmin                          | HEXAL AG<br>Industriestraße 25<br>83607 Holzkirchen<br>DEUTSCHLAND                                     | EU/1/09/589/001-016<br>EU/1/09/589/017-018 | Kapsler, hårde<br>Oral opløsning | N06DA03                                         | 15.12.2009            |
| 11.12.2009            | Rivastigmine Sandoz   | Rivastigmin                          | Sandoz Pharmaceuticals GmbH<br>Raiffeisenstraße 11<br>83607 Holzkirchen<br>DEUTSCHLAND                 | EU/1/09/599/001-016<br>EU/1/09/599/017-018 | Kapsler, hårde<br>Oral opløsning | N06DA03                                         | 15.12.2009            |
| 23.12.2009            | Zenas                 | amifampridin                         | EUSA Pharma SAS<br>3 allée des Séquoias<br>69760 Limonest<br>FRANCE                                    | EU/1/09/601/001                            | Tablet                           | N07XX05                                         | 28.12.2009            |
| 23.12.2009            | Sildenafil ratiopharm | sildenafil                           | Ratiopharm GmbH<br>Graf-Arco-Straße 3<br>89079 Ulm<br>DEUTSCHLAND                                      | EU/1/09/603/001-012                        | Filmovertrukket tablet           | G04BE03                                         | 28.12.2009            |

## — Ændring af markedsføringstilladelse (artikel 13 i forordning (EF) nr. 26/2004): godkendt

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                                   | Nummer i EF-registret                      | Dato for notifikation |
|-----------------------|------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-----------------------|
| 3.12.2009             | Champix          | Pfizer Ltd<br>Ramsgate Road<br>Sandwich<br>Kent<br>CT13 9NJ<br>UNITED KINGDOM                                            | EU/1/06/360/001-013                        | 7.12.2009             |
| 3.12.2009             | Rasilez          | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex<br>RH12 5AB<br>UNITED KINGDOM                   | EU/1/07/405/001-040                        | 7.12.2009             |
| 8.12.2009             | Xigiris          | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>NEDERLAND                                                 | EU/1/02/225/001-002                        | 10.12.2009            |
| 8.12.2009             | Renagel          | Genzyme Europe B.V.<br>Gooimeer 10<br>1411 DD Naarden<br>NEDERLAND                                                       | EU/1/99/123/005-013                        | 10.12.2009            |
| 9.12.2009             | Stocrin          | Merck Sharp & Dohme Ltd<br>Hertford Road<br>Hoddesdon<br>Hertfordshire<br>EN11 9BU<br>UNITED KINGDOM                     | EU/1/99/111/001-005<br>EU/1/99/111/008-011 | 11.12.2009            |
| 9.12.2009             | Sustiva          | Bristol-Myers Squibb Pharma<br>EEIG<br>Uxbridge Business Park<br>Sanderson Road<br>Uxbridge<br>UB8 1DH<br>UNITED KINGDOM | EU/1/99/110/001-005<br>EU/1/99/110/008-010 | 11.12.2009            |
| 9.12.2009             | Pandemrix        | GlaxoSmithKline Biologicals S.A.<br>Rue de l'Institut 89<br>1330 Rixensart<br>BELGIQUE                                   | EU/1/08/452/001                            | 11.12.2009            |
| 10.12.2009            | Effentora        | Cephalon Europe<br>5 rue Charles Martigny<br>94700 Maisons-Alfort<br>FRANCE                                              | EU/1/08/441/001-010                        | 14.12.2009            |
| 10.12.2009            | Effentora        | Cephalon Europe<br>5 rue Charles Martigny<br>94700 Maisons-Alfort<br>FRANCE                                              | EU/1/08/441/001-010                        | 14.12.2009            |
| 10.12.2009            | Synflorix        | GlaxoSmithKline Biologicals S.A.<br>Rue de l'Institut 89<br>1330 Rixensart<br>BELGIQUE                                   | EU/1/09/508/001-010                        | 14.12.2009            |

| Dato for beslutningen | Lægemidlets navn            | Indehaver af markedsføringstilladelsen                                                                                                                       | Nummer i EF-registret | Dato for notifikation |
|-----------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| 10.12.2009            | Truvada                     | Gilead Sciences International Limited<br>Cambridge<br>CB21 6GT<br>UNITED KINGDOM                                                                             | EU/1/04/305/001-002   | 14.12.2009            |
| 10.12.2009            | Fendrix                     | GlaxoSmithKline Biologicals S.A.<br>Rue de l'Institut 89<br>1330 Rixensart<br>BELGIQUE                                                                       | EU/1/04/299/001-003   | 14.12.2009            |
| 10.12.2009            | EVOLTRA                     | Genzyme Europe B.V.<br>Gooimeer 10<br>1411 DD Naarden<br>NEDERLAND                                                                                           | EU/1/06/334/001-005   | 14.12.2009            |
| 10.12.2009            | Revatio                     | Pfizer Limited<br>Sandwich<br>Kent<br>CT13 9NJ<br>UNITED KINGDOM                                                                                             | EU/1/05/318/002       | 24.12.2009            |
| 11.12.2009            | Kivexa                      | Glaxo Group Ltd<br>Greenford<br>Middlesex<br>UB6 0NN<br>UNITED KINGDOM                                                                                       | EU/1/04/298/001-003   | 16.12.2009            |
| 11.12.2009            | Clopidogrel<br>Mylan Pharma | Apotex Europe B.V.<br>Darwingweg 20<br>2333 CR Leiden<br>NEDERLAND<br><br>Mylan S.A.S.<br>117 allée des Parcs<br>69800 Saint Priest<br>FRANCE                | EU/1/09/568/001-018   | 16.12.2009            |
| 11.12.2009            | Rivastigmine<br>1A Pharma   | 1A Pharma GmbH<br>Keltenring 1+3<br>82041 Oberhaching<br>DEUTSCHLAND                                                                                         | EU/1/09/585/001-018   | 16.12.2009            |
| 11.12.2009            | EVICEL                      | OMRIX biopharmaceuticals S.A./<br>N.V.<br>Chaussée de Waterloo/Water-<br>loosesteenweg 200<br>1640 Rhode-St-Genèse/Sint-<br>Genesius-Rode<br>BELGIQUE/BELGIË | EU/1/08/473/001-003   | 15.12.2009            |
| 11.12.2009            | Abseamed                    | Medice Arzneimittel Pütter<br>GmbH & Co KG<br>Kuhloweg 37<br>58638 Iserlohn<br>DEUTSCHLAND                                                                   | EU/1/07/412/001-020   | 15.12.2009            |
| 14.12.2009            | Efient                      | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>NEDERLAND                                                                                     | EU/1/08/503/001-016   | 16.12.2009            |

| Dato for beslutningen | Lægemidlets navn      | Indehaver af markedsføringstilladelsen                                                                                                                                                             | Nummer i EF-registret | Dato for notifikation |
|-----------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| 14.12.2009            | Exalief               | BIAL-Portela & Ca, SA<br>A Av. da Siderurgia Nacional<br>4745-457 S. Mamede do<br>Coronado<br>PORTUGAL                                                                                             | EU/1/09/520/001-020   | 17.12.2009            |
| 14.12.2009            | Zebinix               | BIAL-Portela & Ca, SA<br>A Av. da Siderurgia Nacional<br>4745-457 S. Mamede do<br>Coronado<br>PORTUGAL                                                                                             | EU/1/09/514/001-020   | 17.12.2009            |
| 16.12.2009            | REVLIMID              | Celgene Europe Limited<br>Riverside House<br>Riverside Walk<br>Windsor<br>Berkshire<br>SL4 1NA<br>UNITED KINGDOM                                                                                   | EU/1/07/391/001-004   | 18.12.2009            |
| 18.12.2009            | Docetaxel<br>Winthrop | Aventis Pharma S.A.<br>20 avenue Raymond Aron<br>92165 Antony Cedex<br>FRANCE                                                                                                                      | EU/1/07/384/001-004   | 22.12.2009            |
| 18.12.2009            | Emtriva               | Gilead Sciences International<br>Limited<br>Cambridge<br>CB21 6GT<br>UNITED KINGDOM                                                                                                                | EU/1/03/261/003       | 22.12.2009            |
| 18.12.2009            | Adenuric              | Ipsen Pharma<br>65 quai Georges Gorse<br>92100 Boulogne-Billancourt<br>FRANCE<br><br>Menarini International Operations<br>Luxembourg S.A.<br>1, avenue de la Gare<br>1611 Luxembourg<br>LUXEMBOURG | EU/1/08/447/001-004   | 22.12.2009            |
| 18.12.2009            | Aloxi                 | Helsinn Birex Pharmaceuticals<br>Ltd<br>Damastown<br>Mulhuddart<br>Dublin 15<br>IRELAND                                                                                                            | EU/1/04/306/001       | 22.12.2009            |
| 16.12.2009            | Binocrit              | Sandoz GmbH<br>Biochemiestraße 10<br>6250 Kundl<br>ÖSTERREICH                                                                                                                                      | EU/1/07/410/001-026   | 18.12.2009            |
| 16.12.2009            | Epoetin alfa<br>hexal | Hexal AG.<br>Industriestraße 25<br>83607 Holzkirchen<br>DEUTSCHLAND                                                                                                                                | EU/1/07/411/001-026   | 21.12.2009            |
| 16.12.2009            | Silapo                | STADA Arzneimittel AG<br>Stadastraße 2—18<br>61118 Bad Vilbel<br>DEUTSCHLAND                                                                                                                       | EU/1/07/432/001-022   | 18.12.2009            |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                                 | Nummer i EF-registret                                                                                                                         | Dato for notifikation |
|-----------------------|------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| 18.12.2009            | Litak            | Lipomed GmbH<br>Hegenheimer Straße 2<br>79576 Weil/Rhein<br>DEUTSCHLAND                                                | EU/1/04/275/001-002                                                                                                                           | 22.12.2009            |
| 21.12.2009            | AZARGA           | Alcon Laboratories (UK) Ltd.<br>Pentagon Park<br>Boundary Way<br>Hemel Hempstead<br>Herts<br>HP2 7UD<br>UNITED KINGDOM | EU/1/08/482/001-002                                                                                                                           | 23.12.2009            |
| 21.12.2009            | Altargo          | Glaxo Group Limited<br>Glaxo Wellcome House<br>Berkeley Avenue<br>Greenford<br>Middlesex<br>UB6 0NN<br>UNITED KINGDOM  | EU/1/07/390/001-004                                                                                                                           | 24.12.2009            |
| 21.12.2009            | Zyprexa Velotab  | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>NEDERLAND                                               | EU/1/99/125/001-016                                                                                                                           | 23.12.2009            |
| 21.12.2009            | Avastin          | Roche Registration Limited<br>6 Falcon Way<br>Shire Park<br>Welwyn Garden City<br>AL7 1TW<br>UNITED KINGDOM            | EU/1/04/300/001-002                                                                                                                           | 23.12.2009            |
| 21.12.2009            | LYRICA           | Pfizer Ltd<br>Ramsgate Road<br>Sandwich<br>Kent<br>CT13 9NJ<br>UNITED KINGDOM                                          | EU/1/04/279/001-043                                                                                                                           | 24.12.2009            |
| 21.12.2009            | Taxotere         | Aventis Pharma S.A.<br>20 avenue Raymond Aron<br>92165 Antony Cedex<br>FRANCE                                          | EU/1/95/002/001-004                                                                                                                           | 23.12.2009            |
| 21.12.2009            | Zyprexa          | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>NEDERLAND                                               | EU/1/96/022/002<br>EU/1/96/022/004<br>EU/1/96/022/006<br>EU/1/96/022/009-012<br>EU/1/96/022/014<br>EU/1/96/022/016-017<br>EU/1/96/022/019-034 | 23.12.2009            |
| 21.12.2009            | Revasc           | Canyon Pharmaceuticals Ltd<br>20-22 Bedford Row<br>London<br>WC1R 4JS<br>UNITED KINGDOM                                | EU/1/97/043/001-003                                                                                                                           | 11.1.2010             |
| 21.12.2009            | RAPAMUNE         | Wyeth Europa Limited<br>Huntercombe Lane South<br>Taplow<br>Maidenhead<br>Berkshire<br>SL6 0PH<br>UNITED KINGDOM       | EU/1/01/171/001<br>EU/1/01/171/007-010                                                                                                        | 23.12.2009            |

| Dato for beslutningen | Lægemidlets navn           | Indehaver af markedsføringstilladelsen                                                                                   | Nummer i EF-registret | Dato for notifikation |
|-----------------------|----------------------------|--------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| 21.12.2009            | SOLIRIS                    | Alexion Europe S.A.S.<br>25 Boulevard de l'Amiral Bruix<br>75016 Paris<br>FRANCE                                         | EU/1/07/393/001       | 23.12.2009            |
| 21.12.2009            | Vimpat                     | UCB Pharma SA.<br>Allée de la Recherche 66/<br>Researchdreef 60<br>1070 Bruxelles/Brussel<br>BELGIQUE/BELGIË             | EU/1/08/470/001-017   | 28.12.2009            |
| 21.12.2009            | ZONEGRAN                   | Eisai Limited<br>European Knowledge Centre<br>Mosquito Way<br>Hatfield<br>Hertfordshire<br>AL10 9SN<br>UNITED KINGDOM    | EU/1/04/307/001-013   | 24.12.2009            |
| 21.12.2009            | ZYPADHERA                  | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>NEDERLAND                                                 | EU/1/08/479/001-003   | 23.12.2009            |
| 21.12.2009            | Agenerase                  | Glaxo Group Limited<br>Glaxo Wellcome House<br>Berkeley Avenue<br>Greenford<br>Middlesex<br>UB6 0NN<br>UNITED KINGDOM    | EU/1/00/148/001-004   | 23.12.2009            |
| 21.12.2009            | Irbesartan HCT<br>Winthrop | Sanofi Pharma Bristol Myers<br>Squibb SNC<br>174 avenue de France<br>75013 Paris<br>FRANCE                               | EU/1/06/377/001-028   | 23.12.2009            |
| 21.12.2009            | KARVEZIDE                  | Bristol-Myers Squibb Pharma<br>EEIG<br>Uxbridge Business Park<br>Sanderson Road<br>Uxbridge<br>UB8 1DH<br>UNITED KINGDOM | EU/1/98/085/001-034   | 23.12.2009            |
| 21.12.2009            | Tevagrastim                | Teva Generics GmbH<br>Wasstraße 50<br>01445 Radebeul<br>DEUTSCHLAND                                                      | EU/1/08/445/001-014   | 23.12.2009            |
| 21.12.2009            | Avamys                     | Glaxo Group Ltd<br>Greenford<br>Middlesex<br>UB6 0NN<br>UNITED KINGDOM                                                   | EU/1/07/434/001-003   | 24.12.2009            |
| 21.12.2009            | Thelin                     | Encysive (UK) Limited<br>Alder Castle House<br>10 Noble Street<br>London<br>EC2V 7QJ<br>UNITED KINGDOM                   | EU/1/06/353/001-005   | 24.12.2009            |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                              | Nummer i EF-registret                                     | Dato for notifikation |
|-----------------------|------------------|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|-----------------------|
| 21.12.2009            | Volibris         | Glaxo Group Ltd<br>Greenford<br>Middlesex<br>UB6 0NN<br>UNITED KINGDOM                                              | EU/1/08/451/001-004                                       | 24.12.2009            |
| 22.12.2009            | CELVAPAN         | Baxter AG<br>Industriestraße 67<br>1221 Wien<br>ÖSTERREICH                                                          | EU/1/08/506/001                                           | 23.12.2009            |
| 22.12.2009            | Pandemrix        | GlaxoSmithKline Biologicals S.A.<br>Rue de l'Institut 89<br>1330 Rixensart<br>BELGIQUE                              | EU/1/08/452/001                                           | 23.12.2009            |
| 22.12.2009            | Stelara          | Janssen-Cilag International NV<br>Turnhoutseweg 30<br>2340 Beerse<br>BELGIË                                         | EU/1/08/494/001-002                                       | 24.12.2009            |
| 22.12.2009            | Tasigna          | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex<br>RH12 5AB<br>UNITED KINGDOM              | EU/1/07/422/001-004                                       | 24.12.2009            |
| 22.12.2009            | Replagal         | Shire Human Genetic Therapies<br>AB<br>Svärdvägen 11D<br>SE-182 33 Danderyd<br>SVERIGE                              | EU/1/01/189/001-006                                       | 28.12.2009            |
| 22.12.2009            | Evra             | Janssen-Cilag International NV<br>Turnhoutseweg 30<br>2340 Beerse<br>BELGIË                                         | EU/1/02/223/001-003                                       | 24.12.2009            |
| 22.12.2009            | Crixivan         | Merck Sharp & Dohme Ltd<br>Hertford Road<br>Hoddesdon<br>Hertfordshire<br>EN11 9BU<br>UNITED KINGDOM                | EU/1/96/024/001-005<br>EU/1/96/024/008<br>EU/1/96/024/010 | 24.12.2009            |
| 22.12.2009            | Onsior           | Novartis Animal Health UK Ltd<br>Frimley Business Park<br>Frimley/Camberley<br>Surrey<br>GU16 7SR<br>UNITED KINGDOM | EU/2/08/089/001-021                                       | 24.12.2009            |
| 22.12.2009            | RELISTOR         | Wyeth Europa Limited<br>Huntercombe Lane South<br>Taplow<br>Maidenhead<br>Berkshire<br>SL6 0PH<br>UNITED KINGDOM    | EU/1/08/463/001-003                                       | 24.12.2009            |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                       | Nummer i EF-registret                  | Dato for notifikation |
|-----------------------|------------------|--------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------------|
| 23.12.2009            | Tractocile       | Ferring Pharmaceuticals A/S<br>Kay Fiskers Plads 11<br>2300 Copenhagen S<br>DANMARK                          | EU/1/99/124/001-002                    | 28.12.2009            |
| 23.12.2009            | Biograstim       | CT Arzneimittel GmbH<br>Lengeder Straße 42a<br>13407 Berlin<br>DEUTSCHLAND                                   | EU/1/08/450/001-010                    | 29.12.2009            |
| 23.12.2009            | Retacrit         | HOSPIRA Enterprises B.V.<br>Taurusavenue 19-21b<br>2132 LS Hoofddorp<br>NEDERLAND                            | EU/1/07/431/001-025                    | 31.12.2009            |
| 23.12.2009            | TORISEL          | Wyeth Europa Ltd<br>Huntercombe Lane South<br>Taplow<br>Maidenhead<br>Berkshire<br>SL6 0PH<br>UNITED KINGDOM | EU/1/07/424/001                        | 4.1.2010              |
| 23.12.2009            | IVEMEND          | Merck Sharp & Dohme Limited<br>Hertford Road<br>Hoddesdon<br>Hertfordshire<br>EN11 9BU<br>UNITED KINGDOM     | EU/1/07/437/001-002                    | 4.1.2010              |
| 23.12.2009            | Alisade          | Glaxo Group Ltd, Greenford<br>Middlesex<br>UB6 0NN<br>UNITED KINGDOM                                         | EU/1/08/474/001-003                    | 4.1.2010              |
| 23.12.2009            | Focetria         | Novartis Vaccines and Diagnostics S.r.l.<br>Via Fiorentina 1<br>Siena SI<br>ITALIA                           | EU/1/07/385/001-002<br>EU/1/07/385/004 | 28.12.2009            |

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— Ændring af markedsføringstilladelse (artikel 38 i forordning (EF) nr. 726/2004): godkendt

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen                                                                                                                          | Nummer i EF-registret   | Dato for notifikation |
|-----------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|
| 14.12.2009            | Aivlosin         | ECO Animal Health Ltd<br>78 Coombe Road<br>New Malden<br>Surrey<br>KT3 4QS<br>UNITED KINGDOM                                                                    | EU/2/04/044/011-012-013 | 16.12.2009            |
| 18.12.2009            | Equioxx          | MERIAL<br>29 avenue Tony Garnier<br>69007 Lyon<br>FRANCE                                                                                                        | EU/2/08/083/002-003     | 22.12.2009            |
| 21.12.2009            | Flexicam         | Dechra Veterinary Products A/S<br>Mekuvej 9<br>7171 Uldum<br>DANMARK<br><br>Omnipharm Ltd<br>The Spire<br>Egypt Road<br>Nottingham<br>NG7 7GD<br>UNITED KINGDOM | EU/2/06/058/001-004     | 23.12.2009            |

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

Det Europæiske Lægemiddelagentur  
7 Westferry Circus  
Canary Wharf  
London  
E14 4HB  
UNITED KINGDOM

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