

Oversigt over fællesskabsbeslutninger om tilladelse til markedsføring af lægemidler fra 1. november 2009 til 30. november 2009

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

(2010/C 22/02)

— Udstedelse af markedsføringstilladelse (artikel 13 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 |
|-----------------------|-------------------------------------|---|---|-----------------------|--------------------------|---|-----------------------|
| 4.11.2009 | Repaglinide Krka | Repaglinide | KRKA, d. d. Novo mesto Šmarješka cesta 6 SI-8501 Novo mesto SLOVENIJA | EU/1/09/579/001-018 | Tablet | A10B X02 | 6.11.2009 |
| 4.11.2009 | Copalia HCT | Amlodipinbesylat/ valsartan/hydrochlort- hiazid | Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM | EU/1/09/575/001-060 | Filmovertrukket tablet | C09DX01 | 6.11.2009 |
| 4.11.2009 | Dafiro HCT | Amlodipinbesylat/ valsartan/hydrochlort- hiazid | Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM | EU/1/09/574/001-060 | Filmovertrukket tablet | C09DX01 | 6.11.2009 |
| 26.11.2009 | Multaq | Dronedaron | Sanofi-Aventis 174 avenue de France 75013 Paris FRANCE | EU/1/09/591/001-004 | Filmovertrukne tabletter | Ikke relevant | 1.12.2009 |
| 26.11.2009 | Irbesartan/Hydrochlorothiazide Teva | Irbesartan/hydrochlort- hiazid | Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND | EU/1/09/583/001-072 | Filmovertrukket tablet | C09D A04 | 1.12.2009 |

⁽¹⁾ 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 |
|-----------------------|---------------------|--------------------------------------|--|-----------------------|----------------------------|---|-----------------------|
| 30.11.2009 | Sildenafil Teva | Sildenafil | Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND | EU/1/09/584/001-018 | Filmovertrukket tablet | G04BE03 | 2.12.2009 |
| 30.11.2009 | Nevirapine Teva | Nevirapin | Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND | EU/1/09/598/001-004 | Tablet | J05AG01 | 2.12.2009 |
| 30.11.2009 | Hirobriz Breezhaler | Indacaterolmaleate | Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM | EU/1/09/594/001-010 | Inhalationspulver i kapsel | Ikke relevant | 2.12.2009 |
| 30.11.2009 | Onbrez Breezhaler | Indacaterolmaleate | Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM | EU/1/09/593/001-010 | Inhalationspulver i kapsel | Ikke relevant | 2.12.2009 |
| 30.11.2009 | Oslif Breezhaler | Indacaterolmaleate | Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM | EU/1/09/586/001-010 | Inhalationspulver i kapsel | Ikke relevant | 2.12.2009 |
| 30.11.2009 | Zutectra | Humant hepatitis B Immunoglobulin | Biotest Pharma GmbH Landsteinerstr. 5 63303 Dreieich DEUTSCHLAND | EU/1/09/600/001 | Injektionsvæske, opløsning | J06BB04 | 2.12.2009 |

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

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|---|---|--|-----------------------|
| 4.11.2009 | Intelence | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/08/468/001 | 6.11.2009 |
| 4.11.2009 | Optisulin | Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND | EU/1/00/133/001-032 | 6.11.2009 |
| 4.11.2009 | Lantus | Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND | EU/1/00/134/001-037 | 6.11.2009 |
| 4.11.2009 | Ketek | Aventis Pharma S.A. 20 avenue Raymond Aron 92160 Antony FRANCE | EU/1/01/191/001-005 | 6.11.2009 |
| 4.11.2009 | Osseor | Les Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE | EU/1/04/287/001-006 | 6.11.2009 |
| 4.11.2009 | Protelos | Les Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE | EU/1/04/288/001-006 | 6.11.2009 |
| 5.11.2009 | Abilify | Otsuka Pharmaceutical Europe Ltd Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU UNITED KINGDOM | EU/1/04/276/001-020 EU/1/04/276/024-036 | 10.11.2009 |
| 5.11.2009 | Tyverb | Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/07/440/001-002 | 9.11.2009 |
| 5.11.2009 | Pre-pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals | GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE | EU/1/08/478/001 | 9.11.2009 |
| 5.11.2009 | Celsentri | Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM | EU/1/07/418/001-010 | 9.11.2009 |
| 5.11.2009 | Invega | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/07/395/001-095 | 9.11.2009 |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|------------------|---|--|-----------------------|
| 5.11.2009 | Foscan | Biolitec Pharma Ltd United Drug House Magna Drive Dublin 24 IRELAND | EU/1/01/197/003-005 | 9.11.2009 |
| 6.11.2009 | Fosavance | Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM | EU/1/05/310/001-009 | 10.11.2009 |
| 9.11.2009 | Januvia | Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM | EU/1/07/383/001-018 | 11.11.2009 |
| 11.11.2009 | Celvapan | Baxter AG Industriestraße 67 1221 Wien ÖSTERREICH | EU/1/08/506/001 | 12.11.2009 |
| 11.11.2009 | Focetria | Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina 1 53100 Siena SI ITALIA | EU/1/07/385/001-002 EU/1/07/385/004 | 12.11.2009 |
| 11.11.2009 | Pandemrix | GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE | EU/1/08/452/001 | 12.11.2009 |
| 11.11.2009 | Insuman | Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND | EU/1/97/030/028-195 | 13.11.2009 |
| 11.11.2009 | PegIntron | Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË | EU/1/00/131/001-050 | 13.11.2009 |
| 11.11.2009 | Soliris | Alexion Europe S.A.S. 25 boulevard de l'Amiral Bruix 75016 Paris FRANCE | EU/1/07/393/001 | 13.11.2009 |
| 11.11.2009 | Rebetol | Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË | EU/1/99/107/001-005 | 13.11.2009 |
| 12.11.2009 | Intence | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/08/468/001 | 17.11.2009 |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|-----------------------|--|--|-----------------------|
| 12.11.2009 | IntronA | Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË | EU/1/99/127/001-044 | 17.11.2009 |
| 12.11.2009 | ViraferonPeg | Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË | EU/1/00/132/001-050 | 17.11.2009 |
| 19.11.2009 | IntronA | Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË | EU/1/99/127/031-039 | 23.11.2009 |
| 19.11.2009 | Clopidogrel Pharma | Teva Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND HCS bvba, H. Kennisstraat 53 2650 Edegem BELGIË | EU/1/09/561/001-009 | 23.11.2009 |
| 20.11.2009 | Circadin | RAD Neurim Pharmaceuticals EEC Limited One Forbury Square The Forbury, Reading Berkshire RG1 3EB UNITED KINGDOM | EU/1/07/392/001-002 | 18.12.2009 |
| 20.11.2009 | Bondronat | Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM | EU/1/96/012/004 EU/1/96/012/009-013 | 24.11.2009 |
| 20.11.2009 | Ebixa | H. Lundbeck A/S Ottliavej 9 2500 Valby DANMARK | EU/1/02/219/001-003 EU/1/02/219/005-049 | 24.11.2009 |
| 20.11.2009 | Mycamine | Astellas Pharma Europe B.V. Elisabethhof 19 2353 EW Leiderdorp NEDERLAND | EU/1/08/448/001-002 | 24.11.2009 |
| 20.11.2009 | NeoRecormon | Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM | EU/1/97/031/019-046 | 24.11.2009 |
| 20.11.2009 | MabCampath | Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND | EU/1/01/193/001-002 | 24.11.2009 |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|------------------|---|-----------------------|-----------------------|
| 20.11.2009 | Somavert | Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM | EU/1/02/240/001-004 | 24.11.2009 |
| 20.11.2009 | Reyataz | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM | EU/1/03/267/001-010 | 24.11.2009 |
| 20.11.2009 | Xeristar | Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND | EU/1/04/297/001-008 | 24.11.2009 |
| 20.11.2009 | Regranex | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/99/101/001 | 24.11.2009 |
| 20.11.2009 | Ziagen | Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/99/112/001-002 | 24.11.2009 |
| 20.11.2009 | Cymbalta | Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND | EU/1/04/296/001-009 | 24.11.2009 |
| 20.11.2009 | Angiox | The Medicines Company UK Ltd 115 L Milton Park Abingdon Oxfordshire OX14 4SA UNITED KINGDOM | EU/1/04/289/001-002 | 24.11.2009 |
| 20.11.2009 | Agenerase | Glaxo Group Limited Glaxo Wellcome House Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/00/148/001-004 | 24.11.2009 |
| 20.11.2009 | RoActemra | Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM | EU/1/08/492/001-006 | 24.11.2009 |
| 23.11.2009 | Nexavar | Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND | EU/1/06/342/001 | 25.11.2009 |
| 23.11.2009 | Noxafil | SP Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË | EU/1/05/320/001 | 25.11.2009 |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|------------------|---|-----------------------|-----------------------|
| 23.11.2009 | Pritor | Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND | EU/1/98/089/001-022 | 25.11.2009 |
| 23.11.2009 | Aptivus | Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND | EU/1/05/315/001-002 | 26.11.2009 |
| 23.11.2009 | Exjade | Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM | EU/1/06/356/001-009 | 25.11.2009 |
| 23.11.2009 | Cervarix | GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE | EU/1/07/419/001-012 | 25.11.2009 |
| 23.11.2009 | Trizivir | Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/00/156/002-003 | 25.11.2009 |
| 23.11.2009 | Telzir | Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/04/282/001-002 | 25.11.2009 |
| 23.11.2009 | Azilect | Teva Pharma GmbH Kandelstrasse 10 79199 Kirchzarten DEUTSCHLAND | EU/1/04/304/001-007 | 25.11.2009 |
| 23.11.2009 | Invega | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/07/395/001-095 | 25.11.2009 |
| 23.11.2009 | Puregon | Organon N.V. Kloosterstraat 6 Postbus 20 5340 BH Oss NEDERLAND | EU/1/96/008/001-041 | 25.11.2009 |
| 23.11.2009 | Kinzalmono | Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND | EU/1/98/091/001-014 | 25.11.2009 |
| 23.11.2009 | Micardis | Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND | EU/1/98/090/001-020 | 26.11.2009 |
| 23.11.2009 | Kaletra | Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM | EU/1/01/172/001-007 | 25.11.2009 |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|------------------|--|--|-----------------------|
| 24.11.2009 | Synagis | Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM | EU/1/99/117/001-002 | 26.11.2009 |
| 24.11.2009 | Alli | Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/07/401/007-010 | 26.11.2009 |
| 25.11.2009 | Kivexa | Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM | EU/1/04/298/001-003 | 27.11.2009 |
| 26.11.2009 | Enbrel | Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM | EU/1/99/126/001-021 | 1.12.2009 |
| 26.11.2009 | Enbrel | Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM | EU/1/99/126/001-021 | 1.12.2009 |
| 26.11.2009 | Diacomit | Biocodex 7 avenue Gallieni 94250 Gentilly FRANCE | EU/1/06/367/001-012 | 1.12.2009 |
| 26.11.2009 | Intelence | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/08/468/001 | 1.12.2009 |
| 26.11.2009 | Abseamed | Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 58638 Iserlohn DEUTSCHLAND | EU/1/07/412/021-026 | 1.12.2009 |
| 27.11.2009 | Pandemrix | GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE | EU/1/08/452/001 | 30.11.2009 |
| 27.11.2009 | Focetria | Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina 1 53100 Siena SI ITALIA | EU/1/07/385/001-002 EU/1/07/385/004 | 30.11.2009 |
| 30.11.2009 | Velcade | Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË | EU/1/04/274/001-002 | 2.12.2009 |

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|--------------------|---|-----------------------|-----------------------|
| 30.11.2009 | Champix | Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM | EU/1/06/360/001-013 | 2.12.2009 |
| 30.11.2009 | Adcirca | Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND | EU/1/08/476/001-006 | 2.12.2009 |
| 30.11.2009 | Docetaxel Winthrop | Aventis Pharma S.A. 20 avenue Raymond Aron 92165 Antony Cedex FRANCE | EU/1/07/384/003-004 | 2.12.2009 |
| 30.11.2009 | Taxotere | Aventis Pharma S.A. 20 avenue Raymond Aron 92165 Antony Cedex FRANCE | EU/1/95/002/003-004 | 2.12.2009 |

— **Tilbagekaldelse af markedsføringstilladelse (artikel 13 forordning (EF) nr. 726/2004)**

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|--------------------|---|-----------------------|-----------------------|
| 11.11.2009 | Irbesartan BMS | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM | EU/1/06/375/001-033 | 13.11.2009 |
| 11.11.2009 | Irbesartan HCT BMS | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM | EU/1/06/369/001-028 | 13.11.2009 |
| 12.11.2009 | Clopidogrel BMS | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM | EU/1/08/464/001-019 | 17.11.2009 |
| 26.11.2009 | Paxene | Norton Healthcare Limited Albert Basin Royal Docks London E16 2QJ UNITED KINGDOM | EU/1/99/113/001-004 | 10.12.2009 |

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

| Dato for beslutningen | Lægemidlets navn | INN-navn (internationale fællesnavn) | Indehaver af markedsførings-tilladelsen | Nummer i EF-registret | Lægemiddelform | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|-----------------------|------------------|--------------------------------------|--|-----------------------|----------------|---|-----------------------|
| 4.11.2009 | Zolvix | Monepantel | Novartis Healthcare A/S Lyngbyvej 172 2100 Copenhagen DANMARK | EU/2/09/101/001-010 | Oral solution | QP52AX09 | 6.11.2009 |

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

| Dato for beslutningen | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|-----------------------|------------------|---|--|-----------------------|
| 18.11.2009 | Dexdomitor | Orion Corporation Orionintie 1 FI-02200 Espoo SUOMI/FINLAND | EU/2/02/033/001-002 | 20.11.2009 |
| 19.11.2009 | Improvac | Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM | EU/2/09/095/001-003 | 23.11.2009 |
| 20.11.2009 | Metacam | Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein DEUTSCHLAND | EU/2/97/004/026 EU/2/97/004/033-034 | 24.11.2009 |
| 23.11.2009 | Halocur | Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND | EU/2/99/013/001-002 | 25.11.2009 |

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:

The European Medicines Agency
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Canary Wharf
London
E14 4HB
UNITED KINGDOM