IV

*(Notices)*

# NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

# EUROPEAN COMMISSION

## Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 July 2010 to 31 August 2010

*(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council* [1]*)*

(2010/C 295/01)

[1] OJ L 136, 30.4.2004, p. 1.

**— Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

| Date of the decision | Name of the medicinal product | INN (International Non-Proprietary Name) | Holder of the marketing authorization | Number of the entry in the Community Register | Pharmaceutical form | ATC code (Anatomical Therapeutic Chemical Code) | Date of notification |
|---|---|---|---|---|---|---|---|
| 5.7.2010 | Daxas | roflumilast | Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland | EU/1/10/636/001-003 | Film-coated tablet | R03DX07 | 8.7.2010 |
| 27.7.2010 | Leflunomide medac | leflunomide | medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstrasse 3, D-20354 Hamburg - Deutschland | EU/1/10/637/001-009 | Film-coated tablet | L04AA13 | 30.7.2010 |
| 27.7.2010 | Ozurdex | dexamethasone | Allergan Pharmaceuticals (Ireland) Ltd, Castlebar Road, Westport, Co. Mayo, Ireland | EU/1/10/638/001 | Intravitreal implant in applicator | S01BA01 | 1.8.2010 |
| 26.8.2010 | VPRIV | Velaglucerase alfa | Shire Pharmaceuticals Ireland Limited 5 Riverside Walk, Citywest Business Campus, Dublin 24, Ireland | EU/1/10/646/001-002 | Powder for solution for infusion | A16AB10 | 30.8.2010 |
| 31.8.2010 | PecFent | Fentanyl | Archimedes Development Ltd Nottingham, NGT7 2TN, United Kingdom | EU/1/10/644/001-004 | Nasal spray, solution | N02AB03 | 6.9.2010 |

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 1.7.2010 | Enbrel | Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/99/126/001-021 | 6.7.2010 |
| 1.7.2010 | Humira | Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom | EU/1/03/256/001-010 | 5.7.2010 |
| 1.7.2010 | Invega | Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België | EU/1/07/395/001-095 | 6.7.2010 |
| 1.7.2010 | Kiovig | Baxter AG Industriestraße 67, A - 1221 Wien, Österreich | EU/1/05/329/001-006 | 5.7.2010 |
| 1.7.2010 | Mirapexin | Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland | EU/1/97/051/001-006<br>EU/1/97/051/009-033 | 5.7.2010 |
| 1.7.2010 | Orencia | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/07/389/001-003 | 5.7.2010 |
| 1.7.2010 | Pradaxa | Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/08/442/001-008 | 5.7.2010 |
| 1.7.2010 | Rapamune | Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/01/171/001<br>EU/1/01/171/007-010 | 5.7.2010 |
| 1.7.2010 | Sifrol | Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/97/050/001-006<br>EU/1/97/050/009-033 | 5.7.2010 |
| 1.7.2010 | Sutent | Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom | EU/1/06/347/001-008 | 5.7.2010 |
| 1.7.2010 | TachoSil | Nycomed Austria GmbH St.-Peter-Strasse 25, A-4020 Linz, Österreich | EU/1/04/277/001-004 | 5.7.2010 |
| 1.7.2010 | Tarceva | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/05/311/001-003 | 5.7.2010 |
| 1.7.2010 | Taxotere | Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France | EU/1/95/002/001-005 | 5.7.2010 |
| 1.7.2010 | Tygacil | Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/06/336/001 | 6.7.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 1.7.2010 | Viagra | Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom | EU/1/98/077/002-004<br>EU/1/98/077/006-008<br>EU/1/98/077/010-019 | 5.7.2010 |
| 2.7.2010 | ellaOne | Laboratoire HRA Pharma 15, rue Béranger, 75003 Paris, France | EU/1/09/522/001 | 6.7.2010 |
| 2.7.2010 | Eucreas | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/425/001-018 | 7.7.2010 |
| 2.7.2010 | Galvus | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/414/001-010<br>EU/1/07/414/018 | 7.7.2010 |
| 2.7.2010 | Intelence | Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België | EU/1/08/468/001 | 7.7.2010 |
| 2.7.2010 | Jalra | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/485/001-011 | 7.7.2010 |
| 2.7.2010 | Myocet | Cephalon Europe 5 Rue Charles Martigny, Maisons Alfort 94700, France | EU/1/00/141/001 | 7.7.2010 |
| 2.7.2010 | NovoMix | Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark | EU/1/00/142/004-005<br>EU/1/00/142/009-022 | 7.7.2010 |
| 2.7.2010 | 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 | 7.7.2010 |
| 2.7.2010 | Pegasys | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/02/221/001-010 | 7.7.2010 |
| 2.7.2010 | Sifrol | Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/97/050/001-006<br>EU/1/97/050/009-033 | 8.7.2010 |
| 2.7.2010 | Tamiflu | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/02/222/001-004 | 7.7.2010 |
| 2.7.2010 | Tarceva | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/05/311/001-003 | 7.7.2010 |
| 2.7.2010 | Torisel | Wyeth Europa Ltd Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH, United Kingdom | EU/1/07/424/001 | 7.7.2010 |
| 2.7.2010 | Velcade | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België | EU/1/04/274/001-002 | 6.7.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 2.7.2010 | Xiliarx | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/486/001-011 | 7.7.2010 |
| 2.7.2010 | Xyrem | UCB Pharma Ltd. 208 Bath Road, Slough, Berkshire SL1 3WE, United Kingdom | EU/1/05/312/001 | 6.7.2010 |
| 2.7.2010 | Zeffix | Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/99/114/001-003 | 8.7.2010 |
| 2.7.2010 | Zyllt | KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/09/553/001-010 | 7.7.2010 |
| 5.7.2010 | Celvapan | Baxter AG Industriestraße 67, A - 1221 Wien, Österreich | EU/1/08/506/001 | 8.7.2010 |
| 5.7.2010 | Ferriprox | Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland | EU/1/99/108/001-003 | 8.7.2010 |
| 5.7.2010 | Icandra | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/484/001-018 | 8.7.2010 |
| 5.7.2010 | Rebetol | Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België | EU/1/99/107/001-005 | 13.7.2010 |
| 5.7.2010 | Relistor | Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/08/463/001-003 | 8.7.2010 |
| 5.7.2010 | Reyataz | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/03/267/001-010 | 8.7.2010 |
| 5.7.2010 | Thelin | Encysive (UK) Limited Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom | EU/1/06/353/001-005 | 8.7.2010 |
| 5.7.2010 | Zomarist | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/483/001-018 | 8.7.2010 |
| 6.7.2010 | Avastin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/04/300/001-002 | 8.7.2010 |
| 6.7.2010 | Docetaxel Winthrop | Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France | EU/1/07/384/001-005 | 8.7.2010 |
| 6.7.2010 | Keppra | UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef, 60, Brussel 1070, België | EU/1/00/146/001-032 | 9.7.2010 |

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|---|---|---|---|---|
| 6.7.2010 | Rapamune | Wyeth Europa Limited 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 | 12.7.2010 |
| 6.7.2010 | Savene | TopoTarget A/S Fruebjergvej 3, Copenhagen 2100, Danmark | EU/1/06/350/001 | 12.7.2010 |
| 7.7.2010 | ReFacto AF | Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/99/103/001-004 | 12.7.2010 |
| 13.7.2010 | BeneFIX | Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/97/047/001-007 | 15.7.2010 |
| 13.7.2010 | Kepivance | Biovitrum AB (publ) SE-112 76 Stockholm, Sverige | EU/1/05/314/001 | 15.7.2010 |
| 22.7.2010 | Thelin | Encysive (UK) Limited Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom | EU/1/06/353/001-005 | 26.7.2010 |
| 27.7.2010 | Baraclude | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/06/343/001-007 | 29.7.2010 |
| 27.7.2010 | Conbriza | Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/09/511/001-004 | 29.7.2010 |
| 27.7.2010 | GONAL-f | Merck Serono Europe Ltd. 56, Marsh Wall, London E14 9TP, United Kingdom | EU/1/95/001/001<br>EU/1/95/001/003-005<br>EU/1/95/001/009<br>EU/1/95/001/012<br>EU/1/95/001/021-022<br>EU/1/95/001/025-028<br>EU/1/95/001/031-035 | 30.7.2010 |
| 27.7.2010 | Iscover | Bristol-Myers Squibb Pharma EEIG 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 | 29.7.2010 |
| 27.7.2010 | MicardisPlus | Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland | EU/1/02/213/013-016<br>EU/1/02/213/020<br>EU/1/02/213/022 | 29.7.2010 |
| 27.7.2010 | Plavix | Sanofi Pharma Bristol-Myers Squibb SNC 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 | 29.7.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 27.7.2010 | Ribavirin Teva | Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/509/001-004 | 30.7.2010 |
| 27.7.2010 | Ribavirin Teva Pharma BV | Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/527/001-016 | 31.7.2010 |
| 27.7.2010 | Zonegran | Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom | EU/1/04/307/001-021 | 29.7.2010 |
| 28.7.2010 | Aranesp | Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland | EU/1/01/185/001-022<br>EU/1/01/185/031-099 | 2.8.2010 |
| 28.7.2010 | DaTSCAN | GE Healthcare Limited Little Chalfont, Bucks HP7 9NA, United Kingdom | EU/1/00/135/001-002 | 2.8.2010 |
| 28.7.2010 | DuoCover | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/10/623/001-015 | 30.7.2010 |
| 28.7.2010 | Dynastat | Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom | EU/1/02/209/001-008 | 2.8.2010 |
| 28.7.2010 | Erbitux | Merck KGaA Frankfurter Straße 250, 64271 Darmstadt, Deutschland | EU/1/04/281/001-005 | 2.8.2010 |
| 28.7.2010 | Fendrix | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/04/299/001-003 | 2.8.2010 |
| 28.7.2010 | Ferriprox | Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland | EU/1/99/108/001-006 | 30.7.2010 |
| 28.7.2010 | Helixate NexGen | Bayer Schering Pharma AG 13342 Berlin, Deutschland | EU/1/00/144/001-004 | 30.7.2010 |
| 28.7.2010 | Herceptin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/00/145/001 | 30.7.2010 |
| 28.7.2010 | Increlex | Ipsen Pharma 65, quai Georges Gorse, 92100 Boulogne-Billancourt, France | EU/1/07/402/001 | 2.8.2010 |
| 28.7.2010 | Invanz | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/02/216/001-002 | 2.8.2010 |
| 28.7.2010 | Invirase | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/96/026/001-002 | 2.8.2010 |

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|---|---|---|---|---|
| 28.7.2010 | Kaletra | Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom | EU/1/01/172/001-007 | 2.8.2010 |
| 28.7.2010 | Kivexa | ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/04/298/001-003 | 2.8.2010 |
| 28.7.2010 | Kogenate Bayer | Bayer Schering Pharma AG 13342 Berlin, Deutschland | EU/1/00/143/001-011 | 30.7.2010 |
| 28.7.2010 | Onsenal | Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/03/259/001-006 | 30.7.2010 |
| 28.7.2010 | Prevenar 13 | Wyeth Lederle Vaccines S.A. Rue du Bosquet, 15 B-1348 Louvain-la-Neuve, Belgique | EU/1/09/590/001-006 | 3.8.2010 |
| 28.7.2010 | Simponi | Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland | EU/1/09/546/001-004 | 2.8.2010 |
| 28.7.2010 | Sprycel | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/06/363/001-011 | 2.8.2010 |
| 28.7.2010 | Tyverb | Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/07/440/001-003 | 2.8.2010 |
| 6.8.2010 | Abilify | Otsuka Pharmaceutical Europe Ltd 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 | 12.8.2010 |
| 6.8.2010 | Arava | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/99/118/001-010 | 10.8.2010 |
| 6.8.2010 | Byetta | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/06/362/001-004 | 10.8.2010 |
| 6.8.2010 | Cervarix | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique | EU/1/07/419/001-012 | 10.8.2010 |
| 6.8.2010 | Crixivan | Merck Sharp & Dohme Ltd 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 | 12.8.2010 |
| 6.8.2010 | DuoPlavin | Sanofi Pharma Bristol-Myers Squibb SNC 174 Avenue de France, F-75013 Paris, France | EU/1/10/619/001-015 | 11.8.2010 |
| 6.8.2010 | Efficib | Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/457/001-016 | 11.8.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 6.8.2010 | Evicel | OMRIX biopharmaceuticals S.A./N.V. 200 Chaussée de Waterloo/Waterloosesteenweg 200, B-1640 Rhode-St-Genèse/B-1640 Sint-Genesius-Rode, Belgique/België | EU/1/08/473/001-003 | 11.8.2010 |
| 6.8.2010 | Ferriprox | Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland | EU/1/99/108/001-006 | 10.8.2010 |
| 6.8.2010 | Grepid | Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα | EU/1/09/535/001-016 | 10.8.2010 |
| 6.8.2010 | Herceptin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/00/145/001 | 12.8.2010 |
| 6.8.2010 | Janumet | Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/455/001-016 | 11.8.2010 |
| 6.8.2010 | Januvia | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/383/001-018 | 12.8.2010 |
| 6.8.2010 | Karvea | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/97/049/001-039 | 10.8.2010 |
| 6.8.2010 | Karvezide | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/98/085/001-034 | 10.8.2010 |
| 6.8.2010 | Mepact | IDM PHARMA SAS 11-15 Quai De Dion Bouton, 92816 Puteaux Cedex, France | EU/1/08/502/001 | 13.8.2010 |
| 6.8.2010 | Mycamine | Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland | EU/1/08/448/001-002 | 10.8.2010 |
| 6.8.2010 | Naglazyme | BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom | EU/1/05/324/001-002 | 10.8.2010 |
| 6.8.2010 | Olanzapine Mylan | Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom | EU/1/08/475/001-034 | 10.8.2010 |
| 6.8.2010 | Rebif | Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom | EU/1/98/063/001-017 | 10.8.2010 |
| 6.8.2010 | Ristaben | Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/10/621/001-018 | 11.8.2010 |

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|---|---|---|---|---|
| 6.8.2010 | Ristfor | Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/10/620/001-016 | 11.8.2010 |
| 6.8.2010 | RotaTeq | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, Lyon 69007, France | EU/1/06/348/001-002 | 10.8.2010 |
| 6.8.2010 | Sildenafil ratiopharm | ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland | EU/1/09/603/001-015 | 11.8.2010 |
| 6.8.2010 | Suboxone | Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België | EU/1/06/359/001-004 | 10.8.2010 |
| 6.8.2010 | Sustiva | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/99/110/001-005<br>EU/1/99/110/008-010 | 10.8.2010 |
| 6.8.2010 | Velmetia | Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/08/456/001-016 | 11.8.2010 |
| 6.8.2010 | Xelevia | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/382/001-018 | 10.8.2010 |
| 10.8.2010 | Trisenox | Cephalon Europe 5 Rue Charles Martigny, 94700 Maisons Alfort, Cedex, France | EU/1/02/204/001 | 12.8.2010 |
| 12.8.2010 | Celvapan | Baxter AG Industriestraße 67, A - 1221 Wien, Österreich | EU/1/08/506/001 | 13.8.2010 |
| 12.8.2010 | Focetria | Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia | EU/1/07/385/001-002<br>EU/1/07/385/004 | 13.8.2010 |
| 12.8.2010 | Pandemrix | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/08/452/001 | 13.8.2010 |
| 16.8.2010 | Fosavance | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/05/310/001-009 | 18.8.2010 |
| 18.8.2010 | alli | Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/07/401/007-011 | 24.8.2010 |
| 18.8.2010 | Binocrit | Sandoz GmbH Biochemiestrasse 10, Kundl 6250, Österreich | EU/1/07/410/001-026 | 20.8.2010 |
| 18.8.2010 | Epoetin alfa Hexal | Hexal AG. Industriestrasse 25, D-83607 Holzkirchen, Deutschland | EU/1/07/411/001-026 | 20.8.2010 |
| 18.8.2010 | Gardasil | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France | EU/1/06/357/001-021 | 20.8.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 18.8.2010 | IDflu | Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France | EU/1/08/507/001-006 | 20.8.2010 |
| 18.8.2010 | Insulin Human Winthrop | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/06/368/001-168 | 20.8.2010 |
| 18.8.2010 | Intanza | Sanofi Pasteur MSD SNC 8, rue Jonas Salk, Lyon 69007, France | EU/1/08/505/001-006 | 20.8.2010 |
| 18.8.2010 | Leflunomide Winthrop | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/09/604/001-010 | 20.8.2010 |
| 18.8.2010 | Neupro | Schwarz Pharma Ltd Shannon, Industrial Estate, Co.Clare, Ireland | EU/1/05/331/001-055 | 20.8.2010 |
| 18.8.2010 | Tesavel | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/435/001-018 | 20.8.2010 |
| 23.8.2010 | Aprovel | Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France | EU/1/97/046/001-039 | 24.8.2010 |
| 23.8.2010 | CoAprovel | Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France | EU/1/98/086/001-034 | 24.8.2010 |
| 23.8.2010 | Silgard | Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/06/358/001-021 | 25.8.2010 |
| 26.8.2010 | Baraclude | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/06/343/001-007 | 31.8.2010 |
| 26.8.2010 | Cayston | Gilead Sciences International Limited Granta Park, Abington, Cambridge CB21 6GT, United Kingdom | EU/1/09/543/001-002 | 31.8.2010 |
| 26.8.2010 | Cerezyme | Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/97/053/001-005 | 30.8.2010 |
| 26.8.2010 | Cimzia | UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef, 60, Brussel 1070, België | EU/1/09/544/001-002 | 30.8.2010 |
| 26.8.2010 | Cubicin | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/05/328/001-004 | 31.8.2010 |
| 26.8.2010 | Docetaxel Teva | Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland | EU/1/09/611/001-002 | 31.8.2010 |
| 26.8.2010 | Elonva | N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland | EU/1/09/609/001-002 | 30.8.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 26.8.2010 | Emtriva | Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom | EU/1/03/261/001-003 | 31.8.2010 |
| 26.8.2010 | Hirobriz Breezhaler | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom | EU/1/09/594/001-010 | 31.8.2010 |
| 26.8.2010 | Kaletra | Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom | EU/1/01/172/001-008 | 31.8.2010 |
| 26.8.2010 | Lyrica | Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom | EU/1/04/279/001-044 | 31.8.2010 |
| 26.8.2010 | Mircera | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/07/400/001-024 | 31.8.2010 |
| 26.8.2010 | Myozyme | Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/06/333/001-003 | 31.8.2010 |
| 26.8.2010 | Nexavar | Bayer Schering Pharma AG 13342 Berlin, Deutschland | EU/1/06/342/001 | 30.8.2010 |
| 26.8.2010 | Onbrez Breezhaler | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/593/001-010 | 31.8.2010 |
| 26.8.2010 | Osseor | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/04/287/001-006 | 31.8.2010 |
| 26.8.2010 | Pradaxa | Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/08/442/001-008 | 30.8.2010 |
| 26.8.2010 | Prepandrix | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/08/453/002 | 31.8.2010 |
| 26.8.2010 | Privigen | CSL Behring GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland | EU/1/08/446/001-006 | 31.8.2010 |
| 26.8.2010 | Protelos | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/04/288/001-006 | 31.8.2010 |
| 26.8.2010 | Revatio | Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom | EU/1/05/318/002 | 31.8.2010 |
| 26.8.2010 | Stalevo | Orion Corporation Orionintie 1, FIN-02200 Espoo, Suomi | EU/1/03/260/001-033 | 30.8.2010 |
| 26.8.2010 | Stelara | Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België | EU/1/08/494/001-004 | 30.8.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 26.8.2010 | Tasigna | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/422/001-004 | 31.8.2010 |
| 26.8.2010 | Telzir | ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/04/282/001-002 | 31.8.2010 |
| 26.8.2010 | Thymanax | Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland | EU/1/08/498/001-008 | 31.8.2010 |
| 26.8.2010 | Valdoxan | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/08/499/001-008 | 31.8.2010 |
| 26.8.2010 | Viramune | Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland | EU/1/97/055/001-004 | 30.8.2010 |
| 26.8.2010 | Zostavax | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France | EU/1/06/341/001-013 | 31.8.2010 |
| 31.8.2010 | Abseamed | Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37, D-58638 Iserlohn, Deutschland | EU/1/07/412/001-026 | 2.9.2010 |
| 31.8.2010 | Actos | Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom | EU/1/00/150/001-030 | 2.9.2010 |
| 31.8.2010 | Adenuric | Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg | EU/1/08/447/001-012 | 3.9.2010 |
| 31.8.2010 | Angiox | The Medicines Company UK Ltd 115 L Milton Park, Abingdon, Oxfordshire, OX14 4SA, United Kingdom | EU/1/04/289/002 | 7.9.2010 |
| 31.8.2010 | Ariclaim | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/283/008-012 | 3.9.2010 |
| 31.8.2010 | Arixtra | Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/02/206/001-035 | 2.9.2010 |
| 31.8.2010 | Avastin | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/04/300/001-002 | 2.9.2010 |
| 31.8.2010 | Corlentor | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/05/317/001-014 | 2.9.2010 |
| 31.8.2010 | Glustin | Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom | EU/1/00/151/001-024 | 2.9.2010 |

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 31.8.2010 | HBVAXPRO | Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France | EU/1/01/183/001<br>EU/1/01/183/004-005<br>EU/1/01/183/007-008<br>EU/1/01/183/011<br>EU/1/01/183/013<br>EU/1/01/183/015<br>EU/1/01/183/018-032 | 2.9.2010 |
| 31.8.2010 | Humira | Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom | EU/1/03/256/001-010 | 3.9.2010 |
| 31.8.2010 | InductOs | Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom | EU/1/02/226/001 | 3.9.2010 |
| 31.8.2010 | Infanrix hexa | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/00/152/001-020 | 3.9.2010 |
| 31.8.2010 | Infanrix penta | GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique | EU/1/00/153/001-010 | 3.9.2010 |
| 31.8.2010 | Isentress | Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/436/001-002 | 6.9.2010 |
| 31.8.2010 | Ivemend | Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom | EU/1/07/437/001-004 | 2.9.2010 |
| 31.8.2010 | Procoralan | Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France | EU/1/05/316/001-014 | 2.9.2010 |
| 31.8.2010 | Truvada | Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom | EU/1/04/305/001-002 | 2.9.2010 |
| 31.8.2010 | Yentreve | Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland | EU/1/04/280/001-008 | 2.9.2010 |

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Rejected**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 27.7.2010 | Osigraft | Howmedica International S. de R.L. Division of Stryker Corporation, Raheen Industrial Estate, Raheen, Limerick, Ireland | EU/1/01/179/001 | 29.7.2010 |

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 1.7.2010 | Ingelvac CircoFLEX | Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland | EU/2/07/079/001-004 | 4.7.2010 |
| 1.7.2010 | Profender | Bayer Animal Health GmbH 51368 Leverkusen, Deutschland | EU/2/05/054/001-031 | 6.7.2010 |
| 1.7.2010 | Suprelorin | VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France | EU/2/07/072/001-004 | 5.7.2010 |
| 2.7.2010 | Cortavance | VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France | EU/2/06/069/001 | 7.7.2010 |
| 2.7.2010 | Metacam | Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland | EU/2/97/004/001<br>EU/2/97/004/003-040 | 7.7.2010 |
| 5.7.2010 | Metacam | Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland | EU/2/97/004/001<br>EU/2/97/004/003-042 | 7.7.2010 |
| 27.7.2010 | Equilis Prequenza | Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/05/056/001-004 | 29.7.2010 |
| 27.7.2010 | Equilis Prequenza Te | Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/05/057/001-004 | 29.7.2010 |
| 27.7.2010 | Equilis Te | Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/05/055/001-002 | 29.7.2010 |
| 6.8.2010 | Fevaxyn Pentofel | Fort Dodge Laboratories Ireland Finisklin Industrial Estate - Sligo, Ireland | EU/2/96/002/001-003 | 12.8.2010 |
| 18.8.2010 | Zulvac 8 Bovis | Fort Dodge Animal Health Ltd Flanders Road, Hedge End, Southampton SO30 4QH, United Kingdom | EU/2/09/105/001-002 | 20.8.2010 |
| 18.8.2010 | Zulvac 8 Ovis | Fort Dodge Animal Health Ltd Flanders Road, Hedge End, Southampton SO30 4QH, United Kingdom | EU/2/09/104/001-002 | 20.8.2010 |
| 26.8.2010 | Advocate | Bayer Animal Health GmbH 51368 Leverkusen, Deutschland | EU/2/03/039/001-030 | 30.8.2010 |
| 26.8.2010 | Meloxidyl | CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France | EU/2/06/070/001-008 | 27.8.2010 |

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Rejected**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 26.8.2010 | Masivet | AB Science S.A. 3 avenue George V, 75008 Paris, France | EU/2/08/087/001-002 | 31.8.2010 |

— **Withdrawal of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

| Date of the decision | Name of the medicinal product | Holder of the marketing authorization | Number of the entry in the Community Register | Date of notification |
|---|---|---|---|---|
| 5.7.2010 | Nobilis Influenza H5N6 | Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/07/076/001-004 | 8.7.2010 |
| 7.7.2010 | Nobilis Influenza H7N1 | Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland | EU/2/07/073/001-004 | 9.7.2010 |
| 22.7.2010 | Medicinal Oxygen Air Liquide Santé | Air Liquide Santé International 10 rue Cognacq-Jay, 75341 Paris Cedex 07, France | EU/2/06/067/001-002 | 26.7.2010 |

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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