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. maj 2012 til 31. maj 2012

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

(2012/C 190/01)

([1]) EUT L 136 af 30.4.2004, 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
7.5.2012	Riluzole Zentiva	Riluzol	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/12/768/001	Filmovertrukket tablet	N07XX02	10.5.2012
10.5.2012	Pixuvri	Pixantron	CTI Life Sciences Ltd Biopark, Broadwater Road, Welwyn Garden City, Hertfordshire AL73AX, United Kingdom	EU/1/12/764/001	Pulver til koncentrat til infusionsvæske, opløsning	L01DB11	14.5.2012
22.5.2012	Docetaxel Accord	Docetaxel	Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF United Kingdom	EU/1/12/769/001-003	Koncentrat till infusionsvaeske, opløsning	L01CD02	25.5.2012
22.5.2012	Docetaxel Kabi	Docetaxel	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire, GU35 0NF, United Kingdom	EU/1/12/770/001-004	Koncentrat till infusionsvaeske, opløsning	L01CD02	25.5.2012

— **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
7.5.2012	Intanza	Sanofi Pasteur MSD SNC 8, rue Jonas Salk, Lyon 69007, France	EU/1/08/505/001-003	9.5.2012
7.5.2012	Ovitrelle	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/165/001-003	9.5.2012
10.5.2012	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	14.5.2012
10.5.2012	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/086/001-034	14.5.2012
10.5.2012	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/642/001-004	14.5.2012
10.5.2012	Irbesartan / Hydrochlorothiazide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/583/001-072	14.5.2012
10.5.2012	Siklos	ADDMEDICA 101, rue Saint Lazare, Paris 75009, France	EU/1/07/397/001-004	14.5.2012
10.5.2012	Telmisartan Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76 78, 220 Hafnarfjörður, Iceland	EU/1/10/639/001-030	14.5.2012
10.5.2012	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/610/001-060	14.5.2012
10.5.2012	Trobalt	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/681/001-013	14.5.2012
14.5.2012	Brilique	AstraZeneca AB Södertälje S 151 85, Sverige	EU/1/10/655/001-006	16.5.2012
14.5.2012	Invega	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/07/395/001-095	16.5.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
14.5.2012	JEVTANA	SANOFI 174, avenue de France, F-75013 Paris, France	EU/1/11/676/001	16.5.2012
14.5.2012	Luveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/155/001-003	16.5.2012
14.5.2012	Possia	AstraZeneca AB Södertälje S 151 85, Sverige	EU/1/10/656/001-006	16.5.2012
14.5.2012	TOBI Podhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/10/652/001-003	16.5.2012
15.5.2012	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/008-013 EU/1/07/400/017-024	17.5.2012
15.5.2012	Topotecan Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633/001-002	17.5.2012
15.5.2012	Vizarsin	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/551/001-027	17.5.2012
22.5.2012	Aerinaze	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/399/001-006	25.5.2012
22.5.2012	Fampyra	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/11/699/001-004	25.5.2012
22.5.2012	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-008 EU/1/06/357/018-021	25.5.2012
22.5.2012	HALAVEN	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertsforshire AL10 9SN, United Kingdom	EU/1/11/678/001-002	25.5.2012
22.5.2012	Hizentra	CSL Behring GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland	EU/1/11/687/001-012	25.5.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
22.5.2012	IDflu	Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France	EU/1/08/507/001-003	25.5.2012
22.5.2012	Pergoveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/07/396/001-003	25.5.2012
22.5.2012	Silgard	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358/001-008 EU/1/06/358/018-021	25.5.2012
22.5.2012	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-005	24.5.2012
22.5.2012	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-005	25.5.2012
22.5.2012	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	25.5.2012
25.5.2012	Benlysta	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/700/001-002	30.5.2012
25.5.2012	Betaferon	Bayer Pharma AG D - 13342 Berlin, Deutschland	EU/1/95/003/003-012	30.5.2012
25.5.2012	Busilvex	Pierre Fabre Médicament 45, Place Abel Gance, 92654 Boulogne Billancourt Cedex, France	EU/1/03/254/002	31.5.2012
25.5.2012	Clopidogrel Teva Pharma B.V.	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/649/001-016	30.5.2012
25.5.2012	Conbriza	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/511/001-005	31.5.2012
25.5.2012	DuoCover	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/10/623/001-015	30.5.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
25.5.2012	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416/001-002	31.5.2012
25.5.2012	Fosavance	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/310/001-009	30.5.2012
25.5.2012	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/576/001-039	30.5.2012
25.5.2012	Ixiaro	Intercell AG Campus Vienna Biocenter 3 A-1030 Wien, Österreich	EU/1/08/501/001-002	31.5.2012
25.5.2012	Keppra	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/00/146/001-032	1.6.2012
25.5.2012	Kinzalkomb	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/02/214/001-015	31.5.2012
25.5.2012	Kinzalmono	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/98/091/001-014	31.5.2012
25.5.2012	Kuvan	Merck Serono Europe Limited 56 Marsh Wall, London E14 9TP, United Kingdom	EU/1/08/481/001-003	30.5.2012
25.5.2012	Lamivudine / Zidovudine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/663/001-002	1.6.2012
25.5.2012	Micardis	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090/001-022	31.5.2012
25.5.2012	MicardisPlus	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/02/213/001-023	31.5.2012
25.5.2012	Neulasta	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/02/227/001-002 EU/1/02/227/004	1.6.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
25.5.2012	Nevirapine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/598/001-004	30.5.2012
25.5.2012	Onduarp	Boehringer Ingelheim International GmbH Binger Str. 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729/001-006	30.5.2012
25.5.2012	Optaflu	Novartis Vaccines and Diagnostics GmbH Emil-von-Behring-Strasse 76, D-35041 Marburg, Deutschland	EU/1/07/394/001-009	31.5.2012
25.5.2012	Osseor	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/287/001-006	30.5.2012
25.5.2012	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	1.6.2012
25.5.2012	Pritor	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/98/089/001-022	30.5.2012
25.5.2012	PritorPlus	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/02/215/001-021	30.5.2012
25.5.2012	Protelos	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/288/001-006	
25.5.2012	Rasilamlo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/686/001-056	30.5.2012
25.5.2012	Rasilez	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	30.5.2012
25.5.2012	Rasilez HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	31.5.2012
25.5.2012	Rasitrio	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/730/001-060	31.5.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
25.5.2012	Riprazo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-040	30.5.2012
25.5.2012	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	1.6.2012
25.5.2012	Rivastigmine Actavis	Actavis Group PTC ehf. ReykjavÍkurvegur 76-78, Hafnarfjörður 220, Iceland	EU/1/11/693/001-016	1.6.2012
25.5.2012	RoActemra	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	31.5.2012
25.5.2012	Sprimeo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-040	31.5.2012
25.5.2012	Sprimeo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/683/001-080	1.6.2012
25.5.2012	Temozolomide Hospira	Hospira UK Ltd. Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/615/001-002 EU/1/10/615/005-006 EU/1/10/615/009-010 EU/1/10/615/013-014 EU/1/10/615/017-018 EU/1/10/615/021-022	31.5.2012
25.5.2012	Tysabri	Elan Pharma International Ltd. Treasury Building, Lower Grand Canal Street, Dublin 2, IRELAND	EU/1/06/346/001	31.5.2012
25.5.2012	Vantavo	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572/001-004 EU/1/09/572/006-008	30.5.2012
25.5.2012	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	31.5.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
25.5.2012	Vistide	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/97/037/001	31.5.2012
25.5.2012	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	30.5.2012
25.5.2012	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	31.5.2012
25.5.2012	Xolair	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/319/001-010	30.5.2012
31.5.2012	Lamivudine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/566/001-005	4.6.2012
31.5.2012	Peyona	CHIESI FARMACEUTICI SpA Via Palermo 26/A, I-43100 Parma, ITALIA	EU/1/09/528/001-002	4.6.2012
31.5.2012	Temozolomide Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/09/606/001-012	4.6.2012

— **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
10.5.2012	Valtropin	BioPartners GmbH Kaiserpassage 11 - D-72764 Reutlingen, Deutschland	EU/1/06/335/001	14.5.2012
25.5.2012	Docefrez	Sun Pharmaceuticals Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/10/630/001-002	31.5.2012
25.5.2012	Intrinsa	Warner Chilcott UK Ltd Old Belfast Road, Millbrook, Larne, County Antrim BT40 2SH, United Kingdom	EU/1/06/352/001-003	31.5.2012

— **Ophævelse af suspension af markedsføringstilladelse (artikel 20 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
25.5.2012	Angiox	The Medicines Company UK Ltd 115 L Milton Park, Abingdon, Oxfordshire, OX14 4SA, United Kingdom	EU/1/04/289/001	31.5.2012
25.5.2012	Caelyx	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/96/011/001-004	31.5.2012
25.5.2012	Luminity	Lantheus MI UK Limited Festival House - 39 Oxford Street - Newbury - Berkshire RG14 1JG - United Kingdom	EU/1/06/361/001-002	31.5.2012
25.5.2012	Mepact	IDM PHARMA SAS 11-15 quai De Dion Bouton, 92816 Puteaux Cedex, France	EU/1/08/502/001	1.6.2012
25.5.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	31.5.2012
25.5.2012	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/07/424/001	30.5.2012
25.5.2012	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	31.5.2012
31.5.2012	Ceplene	EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland	EU/1/08/477/001	4.6.2012

— **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
10.5.2012	Circovac	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/07/075/001-004	14.5.2012
10.5.2012	Netvax	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/09/093/001-002	14.5.2012
22.5.2012	Convenia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/06/059/001-002	30.5.2012
22.5.2012	Equip WNV	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/08/086/001-003	25.5.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
22.5.2012	PRILACTONE	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/07/074/001-006	25.5.2012
25.5.2012	Onsior	Novartis Animal Health UK Ltd Frimley Business Park, Frimley/Camberley, Surrey, GU16 7SR, United Kingdom	EU/2/08/089/001-021	1.6.2012
25.5.2012	Suprelorin	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France	EU/2/07/072/001-004	1.6.2012

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
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