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. april 2012 til 30. april 2012

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

(2012/C 148/01)

([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
13.4.2012	Bronchitol	Mannitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire, SL1 7LW, United Kingdom	EU/1/12/760/001-002	Inhalationspulver i kapsel	R05CB16	18.4.2012
13.4.2012	Sabervel	Irbesartan	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/12/765/001-006	Filmovertrukket tablet	C09CA04	17.4.2012
20.4.2012	Capecitabine Accord	capecitabin	Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF United Kingdom	EU/1/12/762/001-018	Filmovertrukket tablet	L01BC06	25.4.2012
20.4.2012	Capecitabine Krka	capecitabin	KRKA, d.d Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia	EU/1/12/763/001-018	Filmovertrukket tablet	L01BC06	25.4.2012
20.4.2012	Capecitabine Teva	capecitabin	TEVA Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/12/761/001-002	Filmovertrukket tablet	L01BC06	25.4.2012
20.4.2012	Nimenrix	Meningokokgruppe A, C, W-135 og Y konjugeret vaccine	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/12/767/001-007	Pulver og solvens til opløsning, injektion	J07AH08	25.4.2012
20.4.2012	SANCUSO	Granisetron	ProStrakan Limited Galabank Business Park, Galashiels, TD1 1QH, United Kingdom	EU/1/12/766/001	Depotplaster	A04AA02	25.4.2012

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
20.4.2012	Zoledronic acid Actavis	Zoledronsyre	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, Hafnarfjörður 220, Iceland	EU/1/12/759/001-003	Koncentrat till infusionsvaeske, opløsning	M05BA08	26.4.2012
24.4.2012	Signifor	pasireotid	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/12/753/001-012	Injektionsvœske, opløsning	H01CB05	27.4.2012

— **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
3.4.2012	Kinzalkomb	Bayer Pharma AG 13342 Berlin Deutschland	EU/1/02/214/001-015	5.4.2012
4.4.2012	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead Berkshire SL6 4XE, United Kingdom	EU/1/03/256/001-010	10.4.2012
4.4.2012	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/069/001a-001b EU/1/98/069/002a-002b EU/1/98/069/003a-003b EU/1/98/069/004a-004b EU/1/98/069/005a-005b EU/1/98/069/006a-006b EU/1/98/069/007a-007b EU/1/98/069/008-010 EU/1/98/069/011a-011b EU/1/98/069/012	11.4.2012
4.4.2012	Rebetol	Schering Plough Europe Clos du Lynx 5, 1200 Bruxelles, Belgique – Lynx Binnenhof 5, 1200 Brussel, België	EU/1/99/107/001-005	11.4.2012
4.4.2012	Telzir	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/04/282/001-002	11.4.2012
10.4.2012	Vedrop	Orphan Europe SARL Immeuble Le Wilson - 70 Avenue du Général de Gaulle - F 92 800 Puteaux - France	EU/1/09/533/001-003	12.4.2012
13.4.2012	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/07/387/001-026	17.4.2012
13.4.2012	alli	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/401/007-016	17.4.2012
13.4.2012	Champix	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/360/001-013	17.4.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
13.4.2012	Evoltra	Genzyme Europe BV Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/06/334/001-005	17.4.2012
13.4.2012	Foscan	Biolitec pharma Ltd United Drug House, Magna Drive, Dublin 24, Ireland	EU/1/01/197/003-005	17.4.2012
13.4.2012	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	17.4.2012
13.4.2012	Prometax	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/092/001-026	17.4.2012
13.4.2012	Revatio	Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/05/318/001	17.4.2012
13.4.2012	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex, UB11 1DB, United Kingdom	EU/1/07/391/001-004	17.4.2012
13.4.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	17.4.2012
13.4.2012	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/440/001-006	17.4.2012
13.4.2012	Viramune	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/97/055/001-009	17.4.2012
13.4.2012	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	17.4.2012
20.4.2012	Abraxane	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex, UB11 1DB, United Kingdom	EU/1/07/428/001	24.4.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
20.4.2012	Aclasta	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/308/001-002	25.4.2012
20.4.2012	Aflunov	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/658/001-002	26.4.2012
20.4.2012	Altargo	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/390/001-004	26.4.2012
20.4.2012	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285/001-036	26.4.2012
20.4.2012	Ceplene	EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland	EU/1/08/477/001	24.4.2012
20.4.2012	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square, The Forbury, Reading, Berkshire RG1 3EB, United Kingdom	EU/1/07/392/001-003	25.4.2012
20.4.2012	Exelon	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/066/001-026	26.3.2012
20.4.2012	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/07/385/001-002 EU/1/07/385/004	26.4.2012
20.4.2012	HALAVEN	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/11/678/001-002	25.4.2012
20.4.2012	Helixate NexGen	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/144/001-005	25.4.2012
20.4.2012	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/03/256/002-010	25.4.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
20.4.2012	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/06/368/001-015 EU/1/06/368/020-024 EU/1/06/368/029-033 EU/1/06/368/037-042 EU/1/06/368/047-051 EU/1/06/368/056-057 EU/1/06/368/088-102 EU/1/06/368/113-150 EU/1/06/368/163-168	25.4.2012
20.4.2012	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030/028-195	26.4.2012
20.4.2012	IOA	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/11/689/001-002	24.4.2012
20.4.2012	Iressa	AstraZeneca AB S 151 85 Sodertalje, Sverige	EU/1/09/526/001-002	26.4.2012
20.4.2012	Kogenate Bayer	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/143/004-013	25.4.2012
20.4.2012	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134/001-037	25.4.2012
20.4.2012	Norvir	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/96/016/001 EU/1/96/016/003-008	26.4.2012
20.4.2012	NovoNorm	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/98/076/004-006 EU/1/98/076/011-013 EU/1/98/076/018-020 EU/1/98/076/022-024	26.3.2012
20.4.2012	Opgenra	Olympus Biotech International Limited Raheen Business Park, Limerick, Ireland	EU/1/08/489/001-002	24.4.2012
20.4.2012	Optimark	Covidien Deutschland GmbH Gewerbepark 1, 93333 Neustadt/Donau, Deutschland	EU/1/07/398/001-014	26.3.2012
20.04.2012	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133/001-032	25.4.2012
20.4.2012	Pelzont	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/460/001-014	25.4.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
20.4.2012	Prandin	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/00/162/003-005 EU/1/00/162/009-011 EU/1/00/162/015-017 EU/1/00/162/019-021	26.4.2012
20.4.2012	Preotact	Nycomed Danmark ApS Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/06/339/001-003	25.4.2012
20.4.2012	Prolia	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	24.4.2012
20.4.2012	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	26.4.2012
20.4.2012	Rasilamlo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/686/001-056	24.4.2012
20.4.2012	Rasilez	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	24.4.2012
20.4.2012	Riprazo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-040	24.4.2012
20.4.2012	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	24.4.2012
20.4.2012	Samsca	Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1LX, United Kingdom	EU/1/09/539/001-004	24.4.2012
20.4.2012	Sebivo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/388/001-003	26.4.2012
20.4.2012	Silodyx	Recordati Ireland Ltd. Raheens East, Ringaskiddy Co. Cork, Ireland	EU/1/09/607/001-014	24.4.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
20.4.2012	Sprimeo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-040	24.4.2012
20.4.2012	Sprimeo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/683/001-080	24.4.2012
20.4.2012	Tracleer	Actelion Registration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220/001-006	26.4.2012
20.4.2012	Tredaptive	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/459/001-014	25.4.2012
20.4.2012	Trevaclyn	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/458/001-014	25.4.2012
20.4.2012	Urorec	Recordati Ireland Ltd. Raheens East, Ringaskiddy Co. Cork, Ireland	EU/1/09/608/001-014	24.4.2012
20.4.2012	Ventavis	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/255/001-008	26.4.2012
20.4.2012	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	25.4.2012
20.4.2012	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	24.4.2012
20.4.2012	Vidaza	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/08/488/001	24.4.2012
20.4.2012	Xenical	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/071/001-006	24.4.2012

Dato for afgørelser	Lægemidlets navn	Indehaver af markedsføringstilladelsen	Nummer i EF-registret	Dato for notifikation
20.4.2012	Yttriga	Eckert & Ziegler Radiopharma GmbH Robert-Rössle-Str. 10, 13125 Berlin, Deutschland	EU/1/05/322/001-002	26.4.2012
20.4.2012	Zoely	Theramex S.r.l. Via Messina 38, 20154 Milano, Italia	EU/1/11/690/001-002	24.4.2012
24.4.2012	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614/001-003	27.4.2012
24.4.2012	Rasilez HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	27.4.2012
24.4.2012	Temomedac	medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstrasse 3, D-20354 Hamburg - Deutschland	EU/1/09/605/001-012	27.4.2012
26.4.2012	Revolade	GlaxoSmithKline Trading Services Limited 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland	EU/1/10/612/001-006	30.4.2012
26.4.2012	Yervoy	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/698/001-002	30.4.2012

— **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
20.4.2012	PhotoBarr	Pinnacle Biologics B.V. p/a Trust Company Amsterdam B.V., Crystal Tower 21st Floor, Orlyplein 10, 1043 DP Amsterdam, Nederland	EU/1/04/272/001-002	25.4.2012
24.4.2012	Refludan	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/97/035/001-004	27.4.2012

— **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
10.4.2012	Slentrol	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/07/071/001-003	12.4.2012
13.4.2012	Cerenia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/06/062/005	17.4.2012
20.4.2012	BTVPUR AlSap 1	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/10/112/001-005	25.4.2012
20.4.2012	BTVPUR AlSap 1-8	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/10/113/001-005	25.4.2012
20.4.2012	Loxicom	Norbrook Laboratories Limited Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090/001-027	24.4.2012
20.4.2012	Meloxivet	Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse, België	EU/2/07/077/001-005	25.4.2012

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:

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