

Taqsisra tad-deċiżjonijiet tal-Komunità dwar l-awtorizzazzjonijiet għat-tqeghid fis-suq fir-rigward ta' prodotti mediċinali mill-1.8.2007 sal-31.8.2007

(Ppubblikat skond l-Artikolu 13 jew l-Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill ⁽¹⁾)

(2007/C 228/02)

— Hruġ ta' awtorizzazzjoni għat-tqeghid fis-suq (Artikolu 13 tar-Regolament (KE) Nru 726/2004): Aċċettat

Data tad-Deciżjoni	Isem tal-prodott mediċinali	INN (Isem internazzjonal Mhux Proprietarju)	Detentur ta' l-awtorizzazzjoni għat-tqeghid fis- suq	Numru tal-partita fir-Reġistru tal-Komunità	Forma Farmaċewtika	Kodiċi ATC (Kodiċi Anato- miku Terapewtiku Kimiku)	Data tan-notifika
3.8.2007	INCRELEX	Mecasermin	Tercia Europe Limited 2 Harbourmaster Place International Financial Services Centre Dublin 1 Ireland	EU/1/07/402/001	Soluzzjoni għall-injez- zjoni	H01AC03	7.8.2007
22.8.2007	Enviage	aliskiren	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/07/406/001-020	Pillola miksija b'rita	C09XA02	24.8.2007
22.8.2007	Riprazo	aliskiren	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/07/409/001-020	Pillola miksija b'rita	C09XA02	24.8.2007
22.8.2007	Sprimeo	aliskiren	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/07/407/001-020	Pillola miksija b'rita	C09XA02	24.8.2007
22.8.2007	Rasilez	aliskiren	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/07/405/001-020	Pillola miksija b'rita	C09XA02	24.8.2007

⁽¹⁾ ĠU L 136, tat-30 ta' April 2004, p. 1.

Data tad-Deciżjoni	Isem tal-prodott mediċinali	INN (Isem internazzjonal Mhux Proprietarju)	Detentur ta' l-awtorizzazzjoni għat-tqeghid fis- suq	Numru tal-partita fir-Reġistru tal-Komunità	Forma Farmaċewtika	Kodiċi ATC (Kodiċi Anato- miku Terapewtiku Kimiku)	Data tan-notifika
22.8.2007	Tekturna	aliskiren	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/07/408/001-020	Pillola miksija b'rita	C09XA02	24.8.2007
22.8.2007	Atriance	nelarabine	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN United Kingdom	EU/1/07/403/001	Soluzzjoni għal infuż- joni	L01BB07	24.8.2007
23.8.2007	Flebogammadif	Immunoglobulin nor- mali uman	Instituto Grifols S.A. Can Guasch 2 — Paret del Vallès E-08150 Barcelona	EU/1/07/404/001-005	Soluzzjoni għall-infuż- joni	J06BA02	27.8.2007
28.8.2007	Abseamed	epoetin alfa	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 D-58638 Iserlohn	EU/1/07/412/001-016	Soluzzjoni għall-injez- zjoni f'siringa mimlija għal-lest	B03XA01	31.8.2007
28.8.2007	Binocrit	epoetin alfa	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl	EU/1/07/410/001-016	Soluzzjoni għall-injez- zjoni f'siringa mimlija għal-lest	B03XA01	31.8.2007
28.8.2007	Epoetin alfa hexal	epoetin alfa	HEXAL Biotech Forschungs GmbH Industriestrasse 25 D-83607 Holzkirchen	EU/1/07/411/001-016	Soluzzjoni għall-injez- zjoni f'siringa mimlija għal-lest	B03XA01	3.9.2007

— **Modifika ta' awtorizzazzjoni ghat-tqeghid fis-suq (Artikolu 13 tar-Regolament (KE) Nru 726/2004): Aċċettata**

Data tad-Deciżjoni	Isem tal-prodott mediċinali	Detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq	Numru tal-partita fir-Registru tal-Komunità	Data tan-notifika
1.8.2007	Keppra	UCB S.A. Allée de la Recherche, 60 B-1070 Bruxelles Researchdreef, 60 B-1070 Brussel UCB Pharma SA. Allée de la Recherche 60 B-1070 Bruxelles Researchdreef, 60 B-1070 Brussel	EU/1/00/146/001-030	3.8.2007
3.8.2007	TachoSil	Nycomed Austria GMBH St.-Peter-Straße 25 A-4020 Linz	EU/1/04/277/001-004	7.8.2007
7.8.2007	BeneFIX	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/97/047/001-007	9.8.2007
10.8.2007	Norvir	Abbott laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/96/016/001 EU/1/96/016/003-004	14.8.2007
10.8.2007	Fasturtec	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/00/170/001-002	14.8.2007
10.8.2007	Ceprothin	Baxter AG Industriestraße 67 A-1220 Vienna	EU/1/01/190/001-002	14.8.2007
10.8.2007	Cellcept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/96/005/001-006	14.8.2007
10.8.2007	Rebif	Serono Europe Limited 56, Marsh Wall London E14 9TP United Kingdom	EU/1/98/063/001-007	14.8.2007
10.8.2007	Tritanrix HepB	GlaxoSmithKline Biologicals S.A. rue de l'Institut, 89 B-1330 Rixensart	EU/1/96/014/001-003	14.8.2007
10.8.2007	Cialis	Lilly ICOS Limited St Bride's House 10 Salisbury Square London EC4Y 8EH United Kingdom	EU/1/02/237/001-008	22.8.2007
20.8.2007	Actos	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/00/150/001-024	22.8.2007

Data tad-Deċiżjoni	Isem tal-prodott medikinali	Detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq	Numru tal-partita fir-Registru tal-Komunità	Data tan-notifika
20.8.2007	Glustin	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/00/151/001-022	22.8.2007
20.8.2007	Competact	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/06/354/001-009	22.8.2007
21.8.2007	Forsteo	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/03/247/001-002	23.8.2007
21.8.2007	Nexavar	Bayer HealthCare AG D-51368 Leverkusen	EU/1/06/342/001	23.8.2007
21.8.2007	Opatanol	Alcon Laboratories (UK) Ltd Pentagon Park Boundary Way Hemel Hempstead Herts HP2 7UD United Kingdom	EU/1/02/217/001-002	23.8.2007
21.8.2007	NeuroBloc	Solstice Neurosciences Ltd Fitzwilton House Wilton Place Dublin 2 Ireland	EU/1/00/166/001-003	23.8.2007
21.8.2007	Avastin	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/04/300/001-002	23.8.2007
21.8.2007	Kiovig	Baxter AG Industriestraße 67 A-1220 Vienna	EU/1/05/329/001-005	23.8.2007
22.8.2007	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/06/363/001-009	24.8.2007
22.8.2007	Luminity	Bristol-Myers Squibb Pharma Belgium Sprl Chaussée de la Hulpe, 185 B-1170 Brussel	EU/1/06/361/001-002	24.8.2007
22.8.2007	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/03/261/001-003	24.8.2007
22.8.2007	Baraclude	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/06/343/001-005	24.8.2007

Data tad-Deċiżjoni	Isem tal-prodott medċinali	Detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq	Numru tal-partita fir-Registru tal-Komunità	Data tan-notifika
23.8.2007	Inovelon	Eisai Limited, 3 Shortlands London W6 8EE United Kingdom	EU/1/06/378/001-016	28.8.2007
23.8.2007	Stocrin	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/99/111/001-011	28.8.2007
23.8.2007	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/99/110/001-009	28.8.2007
23.8.2007	Orfadin	Swedish Orphan International AB Drottninggatan 98 S-111 60 Stockholm	EU/1/04/303/001-003	27.8.2007
27.8.2007	Kivexa	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/04/298/001-002	29.8.2007
27.8.2007	Ziagen	Glaxo Group Ltd Greenford Middlesex UB6 0NN United Kingdom	EU/1/99/112/001-002	29.8.2007
27.8.2007	Rapamune	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/01/171/001 EU/1/01/171/007-012	29.8.2007
27.8.2007	Prezista	Janssen-Cilag International NV Turnhoutseweg, 30 B-2340 Beerse	EU/1/06/380/001	29.8.2007
27.8.2007	NovoMix	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/00/142/004-005 EU/1/00/142/009-022	29.8.2007
27.8.2007	Invanz	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/02/216/001-002	29.8.2007
27.8.2007	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/06/366/001-004	29.8.2007
27.8.2007	Ebixa	H. Lundbeck A/S Ottiliavej 9 DK-2500 Valby	EU/1/02/219/001-015	29.8.2007
29.8.2007	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/99/126/001-018	31.8.2007

Data tad-Deċiżjoni	Isem tal-prodott medikinali	Detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq	Numru tal-partita fir-Reġistru tal-Komunità	Data tan-notifika
28.8.2007	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/296/001-009	31.8.2007
28.8.2007	Xeristar	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/04/297/001-008	31.8.2007
28.8.2007	YENTREVE	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/280/001-008	31.8.2007
28.8.2007	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/283/001-007	31.8.2007
29.8.2007	Stalevo	Orion Corporation Orionintie 1 FIN-02200 Espoo	EU/1/03/260/001-018	31.8.2007
29.8.2007	Exubera	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/05/327/001-018	31.8.2007
29.8.2007	Vistide	Pfizer Enterprises SARL 51, Avenue Kennedy Rond Point du Kirchberg L-1855 Luxembourg	EU/1/97/037/001	31.8.2007
29.8.2007	Evoltra	Bioenvision Limited Bassett House 5 Southwell Park Road Camberley Surrey GU15 3PU United Kingdom	EU/1/06/334/001-004	31.8.2007
29.8.2007	Xelevia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/07/382/001-018	31.8.2007
29.8.2007	Januvia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/07/383/001-018	31.8.2007
29.8.2007	Quixidar	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/207/001-004	31.8.2007
29.8.2007	Quixidar	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/207/001-004	31.8.2007

Data tad-Deciżjoni	Isem tal-prodott medicinali	Detentur ta' l-awtorizzazzjoni għat- tqeghid fis-suq	Numru tal-partita fir- Reġistru tal-Komunità	Data tan-notifika
29.8.2007	Arixtra	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/206/001-004	31.8.2007
29.8.2007	Arixtra	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/206/001-004	31.8.2007
30.8.2007	Fuzeon	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/03/252/001-003	5.9.2007
30.8.2007	BYETTA	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/06/362/001-004	5.9.2007
30.8.2007	Agenerase	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN United Kingdom	EU/1/00/148/001-004	5.9.2007
30.8.2007	Aranesp	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/01/185/001-073	5.9.2007
30.8.2007	NovoRapid	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/99/119/001 EU/1/99/119/003 EU/1/99/119/005-014	5.9.2007
30.8.2007	Nespo	Dompé Biotec S.p.A. Via San Martino 12 I-20122 Milano	EU/1/01/184/001-073	5.9.2007
30.8.2007	Zyprexa	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/96/022/002 EU/1/96/022/004 EU/1/96/022/006 EU/1/96/022/008-012 EU/1/96/022/014 EU/1/96/022/016-017 EU/1/96/022/019-034	5.9.2007
30.8.2007	Zyprexa Velotab	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/99/125/001-016	5.9.2007
30.8.2007	InductOs	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/02/226/001	5.9.2007

Data tad-Deċiżjoni	Isem tal-prodott medikinali	Detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq	Numru tal-partita fir-Registru tal-Komunità	Data tan-notifika
30.8.2007	Aldara	Laboratoires 3M Santé Boulevard de l'Oise F-95029 Cergy Pontoise Cedex Meda AB Pipers väg 2A S-170 73 Solna	EU/1/98/080/001	5.9.2007 5.9.2007
31.8.2007	Karvea	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/97/049/001-039	6.9.2007
31.8.2007	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France F-75013 Paris	EU/1/97/046/001-039	5.9.2007
31.8.2007	CUBICIN	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/05/328/001-002	5.9.2007
31.8.2007	Glustin	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/00/151/001-024	5.9.2007
31.8.2007	Mimpara	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/04/292/001-012	6.9.2007
31.8.2007	Parareg	Dompé Biotec S.p.A. Via San Martino 12 I-20122 Milano	EU/1/04/293/001-012	6.9.2007
31.8.2007	Epivir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/96/015/001-005	6.9.2007
31.8.2007	Zimulti	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/06/345/001-011	6.9.2007
31.8.2007	ACOMPLIA	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/06/344/001-011	6.9.2007
31.8.2007	Prevenar	Wyeth-Lederle Vaccines S.A. Rue du Bosquet B-15-1348 Louvain-La-Neuve	EU/1/00/167/001-007	6.9.2007

— **Sospensjoni ta' awtorizzazzjoni ghat-tqeghid fis-suq (Artikolu 20 tar-Regolament (KE) Nru 726/2004)**

Data tad-Deciżjoni	Isem tal-prodott mediċinali	Detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq	Numru tal-partita fir-Registru tal-Komunità	Data tan-notifika
6.8.2007	Viracept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/97/054/001 EU/1/97/054/003-005	8.8.2007

— **Modifika ta' awtorizzazzjoni ghat-tqeghid fis-suq (Artikolu 38 tar-Regolament (KE) Nru 726/2004): Aċċettata**

Data tad-Deciżjoni	Isem tal-prodott mediċinali	Detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq	Numru tal-partita fir-Registru tal-Komunità	Data tan-notifika
2.8.2007	Dexdomitor	Orion Corporation Orionintie 1 FIN-02200 Espoo	EU/2/02/033/001	6.8.2007
13.8.2007	Advocate	Bayer HealthCare AG D-51368 Leverkusen	EU/2/03/039/001-030	15.8.2007
23.8.2007	PRAC-TIC	Novartis Sanidad Animal S.L. Calle de la Marina, 206 E-08013 Barcelona	EU/2/06/066/001-012	27.8.2007
27.8.2007	Yarvitan	Janssen Animal Health B.V.B.A. Turnhoutseweg, 30 B-2340 Beerse Janssen Pharmaceutica N.V. Turnhoutseweg, 30 B-2340 Beerse	EU/2/06/063/001-003	29.8.2007 29.8.2007

Kull min jixtieq jikkonsulta r-rapport ta' evalwazzjoni pubblika fuq il-prodotti mediċinali inkwistjoni u d-deċiżjonijiet marbuta magħhom għandu jikkuntattja lil:

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