

**Taqsisra tad-deċiżjonijiet tal-Komunità dwar l-awtorizzazzjonijiet ghat-tqeghid fis-suq fir-rigward ta' prodotti mediċinali mill-1 ta' Awwissu 2008 sal-31 ta' Awwissu 2008**

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

(2008/C 245/03)

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

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN<br>(Isem internazzjonal Mhux Proprjetarju) | Detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq  | Numru tal-partita fir-Reġistru tal-Komunità                   | Forma Farmaċewtika  | Kodiċi ATC<br>(Kodiċi Anatomiku Terapewtiku Kimiku) | Data tan-notifika |
|--------------------|-----------------------------|--|--|---|---|---|-------------------|
| 28.8.2008          | INTELENCE                   | etravirine                                     | Janssen-Cilag International NV<br>Turnhoutseweg, 30<br>B-2340 Beerse                       | EU/1/08/468/001   | Pillola   | (Mhux applikabbli)                                  | 1.9.2008          |
| 29.8.2008          | Vimpat                      | Lacosamide                                     | UCB S.A.<br>Allée de la Recherche, 60/Researchdreef, 60<br>B-1070 Bruxelles/B-1070 Brussel | EU/1/08/470/001-013<br>EU/1/08/470/014-015<br>EU/1/08/470/016 | Pillola miksija b'rita<br>Mistura<br>Soluzzjoni għall-infużjoni | N03AX18   | 2.9.2008          |

<sup>(1)</sup> ĠU L 136, 30.4.2004, p. 1.

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

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq   | Numru tal-partita fir-Regjistru tal-Komunità | Data tan-notifika |
|--------------------|-----------------------------|---|--|-------------------|
| 4.8.2008           | Neupro                      | Schwarz Pharma Ltd<br>Shannon<br>Industrial Estate<br>Co.Clare<br>Ireland                         | EU/1/05/331/001-037                          | 6.8.2008          |
| 8.8.2008           | Champix                     | Pfizer Ltd<br>Ramsgate Road<br>Sandwich<br>Kent CT 13 9NJ<br>United Kingdom                       | EU/1/06/360/001-012                          | 12.8.2008         |
| 8.8.2008           | Vectibix                    | Amgen Europe B.V.<br>Minervum 7061<br>4817 ZK Breda<br>Nederland                                  | EU/1/07/423/001-003                          | 12.8.2008         |
| 8.8.2008           | Infanrix hexa               | GlaxoSmithKline Biologicals s.a.<br>rue de l'Institut 89<br>B-1330 Rixensart                      | EU/1/00/152/001-018                          | 12.8.2008         |
| 8.8.2008           | Evista                      | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>Nederland                          | EU/1/98/073/001-004                          | 12.8.2008         |
| 8.8.2008           | Avandamet                   | SmithKline Beecham plc<br>980 Great West Road<br>Brentford<br>Middlesex TW8 9GS<br>United Kingdom | EU/1/03/258/001-022                          | 12.8.2008         |
| 11.8.2008          | Optruma                     | Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>Nederland                          | EU/1/98/074/001-004                          | 13.8.2008         |
| 13.8.2008          | Silapo                      | STADA Arzneimittel AG<br>Stadastrasse 2-18<br>D-61118 Bad Vilbel                                  | EU/1/07/432/001-022                          | 15.8.2008         |
| 13.8.2008          | Retacrit                    | HOSPIRA Enterprises B.V.<br>Taurusavenue 19-21b<br>2132 LS Hoofddorp<br>Nederland                 | EU/1/07/431/001-019                          | 15.8.2008         |
| 13.8.2008          | Humira                      | Abbott Laboratories Ltd<br>Queenborough<br>Kent ME11 5EL<br>United Kingdom                        | EU/1/03/256/001-010                          | 15.8.2008         |
| 13.8.2008          | Hepsera                     | Gilead Sciences International Limited<br>Cambridge CB21 6GT<br>United Kingdom                     | EU/1/03/251/001-002                          | 15.8.2008         |
| 13.8.2008          | Infanrix penta              | GlaxoSmithKline Biologicals s.a.<br>rue de l'Institut 89<br>B-1330 Rixensart                      | EU/1/00/153/001-010                          | 18.8.2008         |
| 13.8.2008          | Cervarix                    | GlaxoSmithKline Biologicals s.a.<br>rue de l'Institut 89<br>B-1330 Rixensart                      | EU/1/07/419/001-009                          | 18.8.2008         |

| 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 |
|--------------------|----------------------------|--|---|-------------------|
| 22.8.2008          | Evista                     | DAIICHI SANKYO EUROPE GmbH<br>Zielstattstrasse 48<br>D-81379 München<br><br>Eli Lilly Nederland B.V.<br>Grootslag 1-5<br>3991 RA Houten<br>Nederland | EU/1/98/073/001-004                         | 26.8.2008         |
| 22.8.2008          | Kaletra                    | Abbott Laboratories Ltd<br>Queenborough<br>Kent ME11 5EL<br>United Kingdom   | EU/1/01/172/001-006                         | 26.8.2008         |
| 22.8.2008          | Baraclude                  | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park<br>Sanderson Road<br>Uxbridge UB8 1DH<br>United Kingdom                                   | EU/1/06/343/001-007                         | 26.8.2008         |
| 22.8.2008          | SUTENT                     | Pfizer Ltd<br>Ramsgate Road<br>Sandwich<br>Kent CT 13 9NJ<br>United Kingdom  | EU/1/06/347/001-006                         | 26.8.2008         |
| 22.8.2008          | Fosavance                  | Merck Sharp & Dohme Ltd<br>Hertford Road<br>Hoddesdon<br>Hertfordshire EN11 9BU<br>United Kingdom  | EU/1/05/310/001-009                         | 26.8.2008         |
| 22.8.2008          | Zalasta                    | KRKA d.d.<br>Šmarješka cesta 6<br>SLO-8501 Novo mesto  | EU/1/07/415/001-056                         | 26.8.2008         |
| 22.8.2008          | Arixtra                    | Glaxo Group Ltd<br>Greenford Road<br>Greenford<br>Middlesex UB6 0NN<br>United Kingdom  | EU/1/02/206/001-035                         | 26.8.2008         |
| 22.8.2008          | Revlimid                   | Celgene Europe Limited<br>Morgan House<br>Madeira Walk<br>Windsor<br>Berkshire SL4 1EP<br>United Kingdom   | EU/1/07/391/001-004                         | 26.8.2008         |
| 25.8.2008          | Abilify                    | Otsuka Pharmaceutical Europe Ltd<br>Hunton House<br>Highbridge Business Park<br>Oxford Road<br>Uxbridge<br>Middlesex UB8 1HU<br>United Kingdom       | EU/1/04/276/001-020<br>EU/1/04/276/024-036  | 27.8.2008         |
| 25.8.2008          | TARGRETIN                  | Eisai Limited<br>3 Shortlands<br>London W6 8EE<br>United Kingdom   | EU/1/01/178/001                             | 27.8.2008         |
| 25.8.2008          | Emselex                    | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex RH12 5AB<br>United Kingdom  | EU/1/04/294/001-028                         | 27.8.2008         |

| 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 |
|--------------------|----------------------------|---|---|-------------------|
| 25.8.2008          | Sifrol                     | Boehringer Ingelheim International GmbH<br>Binger StraÙe 173<br>D-55216 Ingelheim am Rhein            | EU/1/97/050/001-006<br>EU/1/97/050/009-012                        | 27.8.2008         |
| 25.8.2008          | Humira                     | Abbott Laboratories Ltd<br>Queenborough<br>Kent ME11 5EL<br>United Kingdom                            | EU/1/03/256/001-010   | 27.8.2008         |
| 25.8.2008          | Revatio                    | Pfizer Limited<br>Sandwich<br>Kent CT13 9NJ<br>United Kingdom   | EU/1/05/318/001   | 27.8.2008         |
| 25.8.2008          | Prialt                     | Eisai Limited<br>3 Shortlands<br>London W6 8EE<br>United Kingdom                                      | EU/1/04/302/001-004   | 27.8.2008         |
| 25.8.2008          | NovoSeven                  | Novo Nordisk A/S<br>Novo Allé<br>DK-2880 Bagsværd   | EU/1/96/006/001-006   | 27.8.2008         |
| 26.8.2008          | Viagra                     | Pfizer Limited<br>Sandwich<br>Kent CT13 9NJ<br>United Kingdom   | EU/1/98/077/002-004<br>EU/1/98/077/006-008<br>EU/1/98/077/010-019 | 28.8.2008         |
| 28.8.2008          | Rasilez                    | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex RH12 5AB<br>United Kingdom   | EU/1/07/405/001-020   | 1.9.2008          |
| 28.8.2008          | Tekturna                   | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex RH12 5AB<br>United Kingdom   | EU/1/07/408/001-020   | 1.9.2008          |
| 28.8.2008          | Raptiva                    | Serono Europe Limited<br>56 Marsh Wall<br>London E14 9TP<br>United Kingdom                            | EU/1/04/291/001-003   | 1.9.2008          |
| 28.8.2008          | ISENTRESS                  | Merck Sharp & Dohme Limited<br>Hertford Road<br>Hoddesdon<br>Hertfordshire EN11 9BU<br>United Kingdom | EU/1/07/436/001-002   | 1.9.2008          |
| 28.8.2008          | Enviage                    | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex RH12 5AB<br>United Kingdom   | EU/1/07/406/001-020   | 1.9.2008          |
| 28.8.2008          | Sprimeo                    | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex RH12 5AB<br>United Kingdom   | EU/1/07/407/001-020   | 1.9.2008          |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq   | Numru tal-partita fir-Registru tal-Komunità | Data tan-notifika |
|--------------------|-----------------------------|---|---|-------------------|
| 28.8.2008          | Riprazo                     | Novartis Europharm Limited<br>Wimblehurst Road<br>Horsham<br>West Sussex RH12 5AB<br>United Kingdom           | EU/1/07/409/001-020                         | 1.9.2008          |
| 29.8.2008          | Avastin                     | Roche Registration Limited<br>6 Falcon Way<br>Shire Park<br>Welwyn Garden City AL7 1TW<br>United Kingdom      | EU/1/04/300/001-002                         | 2.9.2008          |
| 29.8.2008          | Nespo                       | Dompé Biotec S.p.A.<br>Via San Martino, 12<br>I-20122 Milano  | EU/1/01/184/001-073                         | 2.9.2008          |
| 29.8.2008          | Enbrel                      | Wyeth Europa Limited<br>Huntercombe Lane<br>South Taplow<br>Maidenhead<br>Berkshire SL6 0PH<br>United Kingdom | EU/1/99/126/001-018                         | 1.9.2008          |
| 29.8.2008          | Velcade                     | Janssen-Cilag International NV<br>Turnhoutseweg, 30<br>B-2340 Beerse  | EU/1/04/274/001-002                         | 2.9.2009          |
| 29.8.2008          | Humira                      | Abbott Laboratories Ltd<br>Queenborough<br>Kent ME11 5EL<br>United Kingdom                                    | EU/1/03/256/001-010                         | 2.9.2009          |
| 29.8.2008          | Prezista                    | Janssen-Cilag International NV<br>Turnhoutseweg, 30<br>B-2340 Beerse  | EU/1/06/380/001                             | 2.9.2009          |
| 29.8.2008          | Truvada                     | Gilead Sciences International Limited<br>Cambridge CB21 6GT<br>United Kingdom                                 | EU/1/04/305/001-002                         | 2.9.2009          |
| 29.8.2008          | Neupro                      | Schwarz Pharma Ltd<br>Shannon Industrial Estate<br>Co.Clare<br>Ireland  | EU/1/05/331/038-055                         | 2.9.2009          |
| 29.8.2008          | Neupro                      | Schwarz Pharma Ltd<br>Shannon Industrial Estate<br>Co.Clare<br>Ireland  | EU/1/05/331/001-055                         | 2.9.2009          |

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

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq                          | Numru tal-partita fir-Registru tal-Komunità | Data tan-notifika |
|--------------------|-----------------------------|--|---|-------------------|
| 22.8.2008          | Protopy                     | Astellas Pharma GmbH<br>Neumarkter Str. 61<br>D-81673 München                | EU/1/02/202/001-006                         | 26.8.2008         |
| 28.8.2008          | Quintanrix                  | GlaxoSmithKline Biologicals s.a.<br>rue de l'Institut 89<br>B-1330 Rixensart | EU/1/04/301/001-005                         | 1.9.2008          |

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

| Data tad-deċizzjoni | Isem tal-prodott mediċinali | Detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq   | Numru tal-partita fir-Registru tal-Komunità | Data tan-notifika |
|---------------------|-----------------------------|---|---|-------------------|
| 13.8.2008           | Dexdomitor                  | Orion Corporation<br>Orionintie 1<br>FI-02200 Espoo   | EU/2/02/033/001-002                         | 15.8.2008         |
| 22.8.2008           | Suvaxyn Aujeszky            | Fort Dodge Animal Health Holland<br>C.J. van Houtenlaan 36<br>1381 CP Weesp<br>Nederland  | EU/2/98/009/001-006                         | 26.8.2008         |
| 25.8.2008           | Zubrin                      | Schering-Plough Limited<br>Schering-Plough House<br>Shire Park<br>Welwyn Garden City<br>Hertfordshire AL7 1TW<br>United Kingdom | EU/2/00/028/002-008                         | 27.8.2008         |
| 25.8.2008           | Circovac                    | Merial<br>29, Avenue Tony Garnier<br>F-69007 Lyon   | EU/2/07/075/001-004                         | 27.8.2008         |
| 25.8.2008           | Profender                   | Bayer HealthCare AG<br>D-51368 Leverkusen   | EU/2/05/054/018-031                         | 27.8.2008         |

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

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London E14 4HB  
United Kingdom