

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. lipnja 2013. do 31. srpnja 2013.

(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ⁽¹⁾)

(2013/C 250/02)

⁽¹⁾ SL L 136, 30.4.2004., str. 1.

— Izdavanje odobrenja za stavljanje u promet (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): Prihvaćeno

| Datum odluke | Naziv lijeka | INN (međunarodni nezaštićeni naziv lijeka) | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Farmaceutski oblik | Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova) | Datum obavijesti |
|--------------|----------------------|--|--|---------------------------------|-------------------------|---|------------------|
| 13.6.2013 | Memantine ratiopharm | memantin | ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland | EU/1/13/836 | Filmom obložena tableta | N06DX01 | 17.6.2013 |
| 14.6.2013 | Votrient | Pazopanibklorida | Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/10/628 | Filmom obložena tableta | L01XE11 | 18.6.2013 |
| 21.6.2013 | Capecitabine SUN | Kapecitabin | Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland | EU/1/13/831 | Filmom obložena tableta | L01BC06 | 25.6.2013 |
| 21.6.2013 | Spedra | avanafil | VIVUS B.V. Prins Bernhardplein 200, NL-1097 JB Amsterdam, Nederland | EU/1/13/841 | Tableta | G04BE | 25.6.2013 |
| 21.6.2013 | Xtandi | enzalutamid | Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland | EU/1/13/846 | Kapsula, meka | Pending | 25.6.2013 |
| 24.6.2013 | Nuedexta | dekstrometorfan/kinidin | Jenson Pharmaceutical Services Ltd Carradine House 237 Regents Park Road, London N3 3LF, United Kingdom | EU/1/13/833 | Kapsula, tvrda | N07XX | 26.6.2013 |
| 24.6.2013 | Stayveer | | Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland | EU/1/13/832 | Filmom obložena tableta | C02KX01 | 25.6.2013 |
| 27.6.2013 | MACI | kultivirani karakterizirani autologni hondrociti aplicirani na matriks | Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland | EU/1/13/847 | Matrica za implantaciju | M09AX02 | 1.7.2013 |

| Datum odluke | Naziv lijeka | INN (međunarodni nezaštićeni naziv lijeka) | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Farmaceutski oblik | Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova) | Datum obavijesti |
|--------------|-----------------|--|---|---------------------------------|---|---|------------------|
| 1.7.2013 | Iclusig | ponatiniba | ARIAD Pharma Ltd 2 Temple Back East, Temple Quay, Bristol, BS1 6EG, United Kingdom | EU/1/13/839 | Filmom obložena tableta | L01XE24 | 3.7.2013 |
| 1.7.2013 | Imatinib Accord | Imatinib | Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF, United Kingdom | EU/1/13/845 | Filmom obložena tableta | L01XE01 | 3.7.2013 |
| 12.7.2013 | Erivedge | vismodegib | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/13/848 | Kapsula, tvrda | L01XX43 | 17.7.2013 |
| 25.7.2013 | Lonquex | lipegfilgrastim | Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland | EU/1/13/856 | Otopina za injekciju | L03AA14 | 29.7.2013 |
| 31.7.2013 | Atosiban SUN | atosiban | Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland | EU/1/13/852 | Koncentrat za otopinu za infuziju Otopina za injekciju | G02CX01 | 2.8.2013 |
| 31.7.2013 | Imvanex | modificirani virus vakcine ankara | Bavarian Nordic A/S Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark | EU/1/13/855 | Suspencija za injekciju | J07BX | 5.8.2013 |
| 31.7.2013 | Lojuxta | Lomitapid | Aegerion Pharmaceuticals 37/39 avenue Ledru Rollin, F-75012 Paris, France | EU/1/13/851 | Kapsula, tvrda | C10AX12 | 5.8.2013 |
| 31.7.2013 | PHEBURANE | natrijev fenilbutirat | Lucane Pharma 172 rue de Charonne, 75011 Paris, France | EU/1/13/822/ | Zrnice | A16AX03 | 5.8.2013 |

— Izmjena odobrenja za stavljanje u promet (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): Prihvaćeno

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|--|---------------------------------|------------------|
| 11.6.2013 | IOA | Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland | EU/1/11/689 | 13.6.2013 |
| 11.6.2013 | Rienso | Takeda Pharma A/S PO Box 88, Langebjerg 1, DK-4000 Roskilde, Danmark | EU/1/12/774 | 13.6.2013 |
| 11.6.2013 | Zoely | Theramex S.r.l. Via Messina 38, 20154 Milano, Italia | EU/1/11/690 | 18.6.2013 |
| 13.6.2013 | Abilify | Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Estate, Oxford Road, Uxbridge, Middlesex UB8 1LX, United Kingdom. | EU/1/04/276 | 17.6.2013 |
| 13.6.2013 | Atripla | Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland | EU/1/07/430 | 17.6.2013 |
| 13.6.2013 | Revlimid | Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom | EU/1/07/391 | 17.6.2013 |
| 13.6.2013 | Tysabri | Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom | EU/1/06/346 | 17.6.2013 |
| 21.6.2013 | Bridion | Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland | EU/1/08/466 | 25.6.2013 |
| 21.6.2013 | Brinavess | Cardiome UK Limited Sherborne House, 119-121 Cannon Street, 3rd Floor, London EC4N 5AT, United Kingdom | EU/1/10/645 | 25.6.2013 |
| 21.6.2013 | EDURANT | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België | EU/1/11/736 | 25.6.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--|---|---------------------------------|------------------|
| 21.6.2013 | Eviplera | Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom | EU/1/11/737 | 25.6.2013 |
| 21.6.2013 | Intelligence | Janssen-Cilag International NV Turnhouseweg 30, B-2340 Beerse, België | EU/1/08/468 | 25.6.2013 |
| 21.6.2013 | Javlor | Pierre Fabre Médicament 45, place Abel Gance, F-92100 Boulogne, France | EU/1/09/550 | 25.6.2013 |
| 21.6.2013 | Osseor | Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France | EU/1/04/287 | 25.6.2013 |
| 21.6.2013 | Protelos | Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France | EU/1/04/288 | 25.6.2013 |
| 21.6.2013 | Reyataz | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/03/267 | 25.6.2013 |
| 21.6.2013 | Xenical | Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom | EU/1/98/071 | 25.6.2013 |
| 21.6.2013 | Zerit | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/96/009 | 25.6.2013 |
| 27.6.2013 | Glivec | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/01/198 | 1.7.2013 |
| 27.6.2013 | Levodopa/Carbidopa/Entacapone Orion | Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi | EU/1/11/706 | 1.7.2013 |
| 27.6.2013 | Rasilamlo | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/11/686 | 1.7.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|---|---------------------------------|------------------|
| 27.6.2013 | Rasilez | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/405 | 1.7.2013 |
| 27.6.2013 | Vivanza | Bayer Pharma AG D-13342 Berlin, Deutschland | EU/1/03/249 | 1.7.2013 |
| 1.7.2013 | Ariclaim | Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland | EU/1/04/283 | 3.7.2013 |
| 1.7.2013 | Emtriva | Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom | EU/1/03/261 | 3.7.2013 |
| 1.7.2013 | Fampyra | Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom | EU/1/11/699 | 3.7.2013 |
| 1.7.2013 | Intelence | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België | EU/1/08/468 | 3.7.2013 |
| 1.7.2013 | PREZISTA | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België | EU/1/06/380 | 3.7.2013 |
| 1.7.2013 | Rasilez HCT | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/491 | 3.7.2013 |
| 1.7.2013 | Replagal | Shire Human Genetic Therapies AB Svärdvägen 11D, SE-182 33 Danderyd, Sverige | EU/1/01/189 | 3.7.2013 |
| 1.7.2013 | Stocrin | Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom | EU/1/99/111 | 3.7.2013 |
| 1.7.2013 | Sustiva | Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/99/110 | 3.7.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|--|---------------------------------|------------------|
| 1.7.2013 | Trobalt | Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/11/681 | 3.7.2013 |
| 1.7.2013 | Truvada | Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom | EU/1/04/305 | 3.7.2013 |
| 1.7.2013 | Viread | Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom | EU/1/01/200 | 3.7.2013 |
| 1.7.2013 | Votrient | Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/10/628 | 3.7.2013 |
| 1.7.2013 | Yentreve | Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland | EU/1/04/280 | 3.7.2013 |
| 4.7.2013 | Cymbalta | Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland | EU/1/04/296 | 8.7.2013 |
| 4.7.2013 | Lucentis | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/374 | 8.7.2013 |
| 4.7.2013 | Rasitrio | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/11/730 | 8.7.2013 |
| 4.7.2013 | Xeristar | Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland | EU/1/04/297 | 8.7.2013 |
| 9.7.2013 | Prevenar 13 | Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/1/09/590 | 11.7.2013 |
| 9.7.2013 | Tysabri | Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom | EU/1/06/346 | 11.7.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|------------------------|--|---------------------------------|------------------|
| 15.7.2013 | Benlysta | Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom | EU/1/11/700 | 17.7.2013 |
| 15.7.2013 | Onduarp | Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/11/729 | 17.7.2013 |
| 15.7.2013 | Pradaxa | Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/08/442 | 17.7.2013 |
| 15.7.2013 | Votubia | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/11/710 | 17.7.2013 |
| 17.7.2013 | Iscover | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/98/070 | 19.7.2013 |
| 17.7.2013 | Plavix | Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France | EU/1/98/069 | 19.7.2013 |
| 17.7.2013 | Votubia | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/11/710 | 19.7.2013 |
| 19.7.2013 | Clopidogrel Zentiva | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/08/465 | 23.7.2013 |
| 19.7.2013 | DuoPlavin | Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France | EU/1/10/619 | 23.7.2013 |
| 19.7.2013 | Ratiograstim | ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland | EU/1/08/444 | 23.7.2013 |
| 19.7.2013 | Tevagrastim | Teva GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland | EU/1/08/445 | 23.7.2013 |
| 19.7.2013 | Thalidomide Celgene | Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom | EU/1/08/443 | 23.7.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|-------------------|--|---------------------------------|------------------|
| 25.7.2013 | Aranesp | Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland | EU/1/01/185 | 29.7.2013 |
| 25.7.2013 | Biograstim | CT Arzneimittel GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland | EU/1/08/450 | 29.7.2013 |
| 25.7.2013 | Leflunomide medac | medac Gesellschaft für klinische Spezial- präparate mbH Fehlandtstraße 3, D-20354 Hamburg, Deutschland | EU/1/10/637 | 29.7.2013 |
| 25.7.2013 | Remicade | Janssen Biologics B.V. Einsteinweg 101, NL-2333 CB Leiden, Nederland | EU/1/99/116 | 29.7.2013 |
| 25.7.2013 | Tyverb | Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom | EU/1/07/440 | 29.7.2013 |
| 25.7.2013 | Vectibix | Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland | EU/1/07/423 | 29.7.2013 |
| 25.7.2013 | Zytiga | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België | EU/1/11/714 | 29.7.2013 |
| 26.7.2013 | BYDUREON | Bristol-Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom | EU/1/11/696 | 31.7.2013 |
| 26.7.2013 | DuoCover | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/10/623 | 31.7.2013 |
| 26.7.2013 | Eucreas | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/425 | 30.7.2013 |
| 26.7.2013 | Evicel | Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, B-1831 Diegem, België | EU/1/08/473 | 30.7.2013 |
| 26.7.2013 | Iscover | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/98/070 | 31.7.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|--|---------------------------------|------------------|
| 26.7.2013 | 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 | 30.7.2013 |
| 26.7.2013 | Plavix | Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France | EU/1/98/069 | 30.7.2013 |
| 26.7.2013 | Rasilez | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/405 | 31.7.2013 |
| 26.7.2013 | Rasitrio | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/11/730 | 30.7.2013 |
| 26.7.2013 | Teysuno | Nordic Group B.V. Siriusdreef 22, NL-2132 WT Hoofddorp, Nederland | EU/1/11/669 | 31.7.2013 |
| 31.7.2013 | Aprovel | Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France | EU/1/97/046 | 5.8.2013 |
| 31.7.2013 | CoAprovel | Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France | EU/1/98/086 | 5.8.2013 |
| 31.7.2013 | Copalia | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/372 | 2.8.2013 |
| 31.7.2013 | Copalia HCT | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/575 | 5.8.2013 |
| 31.7.2013 | Dafiro | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/371 | 5.8.2013 |
| 31.7.2013 | Dafiro HCT | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/574 | 2.8.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|---------------------------|--|---------------------------------|------------------|
| 31.7.2013 | Exforge | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/370 | 5.8.2013 |
| 31.7.2013 | Exforge HCT | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/09/569 | 2.8.2013 |
| 31.7.2013 | Galvus | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/07/414 | 5.8.2013 |
| 31.7.2013 | Icandra | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/484 | 5.8.2013 |
| 31.7.2013 | Imprida | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/06/373 | 5.8.2013 |
| 31.7.2013 | Irbesartan HCT Zentiva | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/06/377 | 2.8.2013 |
| 31.7.2013 | Irbesartan Zentiva | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/06/376 | 5.8.2013 |
| 31.7.2013 | Jalra | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/485 | 5.8.2013 |
| 31.7.2013 | Karvea | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/97/049 | 2.8.2013 |
| 31.7.2013 | Karvezide | Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France | EU/1/98/085 | 2.8.2013 |
| 31.7.2013 | Leganto | UCB Manufacturing Ireland Ltd. Shannon Industrial Estate, Co, Clare, Ireland | EU/1/11/695 | 2.8.2013 |
| 31.7.2013 | Neupro | UCB Manufacturing Ireland Ltd. Shannon Industrial Estate, Co, Clare, Ireland | EU/1/05/331 | 2.8.2013 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|---|---------------------------------|------------------|
| 31.7.2013 | ProQuad | Sanofi Pasteur MSD, SNC 8 rue Jonas Salk, F-69007 Lyon, France | EU/1/05/323 | 2.8.2013 |
| 31.7.2013 | VELCADE | Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, Belgijë | EU/1/04/274 | 5.8.2013 |
| 31.7.2013 | Vimpat | UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, Belgijë | EU/1/08/470 | 5.8.2013 |
| 31.7.2013 | Xiliarx | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/486 | 5.8.2013 |
| 31.7.2013 | Zomarist | Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom | EU/1/08/483 | 2.8.2013 |

— **Povlačenje odobrenja za stavljanje u promet (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|--|---------------------------------|------------------|
| 6.6.2013 | Sepioglin | Vaia S.A. 1, 28 Octovriou str., Ag. Varvara 123 51, Athens, Ελλάδα | EU/1/12/754 | 10.6.2013 |

— **Prekid obustave odobrenja za stavljanje u promet (članak 20. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|-----------------------------|--|---------------------------------|------------------|
| 17.7.2013 | Ribavirin Teva | Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland | EU/1/09/509 | 19.7.2013 |
| 17.7.2013 | Ribavirin Teva Pharma BV | Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland | EU/1/09/527 | 19.7.2013 |

— Izdavanje odobrenja za stavljanje u promet (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ⁽¹⁾): Prihvaćeno

| Datum odluke | Naziv lijeka | INN (međunarodni nezaštićeni naziv lijeka) | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Farmaceutski oblik | Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova) | Datum obavijesti |
|--------------|-------------------|---|---|---------------------------------|-------------------------|---|------------------|
| 6.6.2013 | Equilis West Nile | Inaktivirani kimerni flavivirus soj YF-WN | Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland | EU/2/13/151 | Suspencija za injekciju | QI05AA10 | 10.6.2013 |
| 12.7.2013 | ProZinc | Ljudski inzulin | Boehringer Ingelheim Vetmedica GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/2/13/152 | Suspencija za injekciju | QA10AC01 | 16.7.2013 |
| 15.7.2013 | Aftovaxpur Doe | pročišćeni, inaktivirani sojeva virusa koji uzrokuje bolest slinavke i šapa O1 Manisa, O1 BFS, O Taiwan 3/97, A22 Iraq, A24 Cruzeiro, A Turkey 14/98, Asia 1 Shamir | Merial 29 avenue Tony Garnier, F-69007 Lyon, France | EU/2/13/153 | Emulzija za injekciju | QI02AA04 | 17.7.2013 |

⁽¹⁾ SL L 136, 30.4.2004., str. 1.

— **Izmjena odobrenja za stavljanje u promet (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): Prihvaćeno**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|------------------------------|--|---------------------------------|------------------|
| 6.6.2013 | Equioxx | Merial 29 avenue Tony Garnier, F-69007 Lyon, France | EU/2/08/083 | 11.6.2013 |
| 13.6.2013 | Contacera | Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain- La-Neuve, Belgique | EU/2/12/144 | 17.6.2013 |
| 9.7.2013 | Suvaxyn Aujeszky 783 +O/W | Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain- La-Neuve, Belgique | EU/2/98/009 | 11.7.2013 |
| 15.7.2013 | Reconcile | Eli Lilly and Company Ltd Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom | EU/2/08/080 | 19.7.2013 |
| 15.7.2013 | Zactran | Merial 29 avenue Tony Garnier, F-69007 Lyon, France | EU/2/08/082 | 17.7.2013 |
| 26.7.2013 | Zulvac 1+8 Ovis | Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain- La-Neuve, Belgique | EU/2/11/120 | 30.7.2013 |

— **Povlačenje odobrenja za stavljanje u promet (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|--------------|--------------|---|---------------------------------|------------------|
| 21.6.2013 | Ibafin | Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland | EU/2/00/022 | 25.6.2013 |

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

The European Medicines Agency
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