IV

(Informacije)

INFORMACIJE INSTITUCIJ, ORGANOV, URADOV IN AGENCIJ EVROPSKE UNIJE

EVROPSKA KOMISIJA

Povzetek sklepov Evropske unije o dovoljenjih za promet z zdravili od 1. november 2011 do 31. december 2011

(Objavljeno v skladu s členom 13 ali členom 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta [1]*)*

(2012/C 56/01)

[1] UL L 136, 30.4.2004, str. 1.

— **Izdaja dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Odobrena**

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
3.11.2011	Plenadren	hidrokortizon	DuoCort Pharma AB Kullagatan 8-10, S-252 20 Helsingborg, Sveridge	EU/1/11/715/001-002	tableta s prirejenim sproščanjem	H02AB09	14.11.2011
16.11.2011	IOA	Nomegestrol / estradiol	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/11/689/001-002	Filmsko obložene tablete	G03AA14	18.11.2011
16.11.2011	Vyndaqel	tafamidis	Pfizer Specialty UK Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/11/717/001	Kapsula, mehka	N07XX08	18.11.2011
22.11.2011	Rasitrio	aliskiren / amlodipin / hidroklorotiazid	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/730/001-060	Filmsko obložene tablete	C09XA54	24.11.2011
24.11.2011	Desloratadine Teva	desloratadin	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/732/001-013	Filmsko obložene tablete	R06AX27	29.11.2011
24.11.2011	Komboglyze	saksagliptin / metformin	Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/11/731/001-012	Filmsko obložene tablete	A10BD	28.11.2011
24.11.2011	Onduarp	telmisartan / amlodipin	Boehringer Ingelheim International GmbH Binger Str. 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729/001-006	Tableta	C09DB04	28.11.2011

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28.11.2011	Dasselta	desloratadin	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/739/001-008	Filmsko obložene tablete	R06AX27	30.11.2011
28.11.2011	EDURANT	rilpivirin	Janssen Cilag International NV Turnhoutseweg 30, B 2340 Beerse, België	EU/1/11/736/001	Filmsko obložene tablete	J05AG05	30.11.2011
28.11.2011	Eviplera	emtricitabin / rilpivirin (v obliki klorida) / tenofovirdizoproksilat (v obliki fumarata)	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/11/737/001-002	Filmsko obložene tablete	J05AR08	28.11.2011
5.12.2011	Dificlir	fidaksomicin	FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland	EU/1/11/733/001-004	Filmsko obložene tablete	Pending	7.12.2011
5.12.2011	Levetiracetam Actavis Group	Levetiracetam	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, Hafnarfjörður 220, Iceland	EU/1/11/738/001-003	Peroralna raztopina	N03AX14	7.12.2011
7.12.2011	Edarbi	Medoksomilazilsartanata	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/11/734/001-011	Tableta	C09CA09	9.12.2011
7.12.2011	Ipreziv	Medoksomilazilsartanata	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/11/735/001-011	Tableta	C09CA09	9.12.2011
14.12.2011	Ameluz	5-aminolevulinska kislina	Biofrontera Bioscience GmbH Hemmelrather Weg 201, 51377 Leverkusen, Deutschland	EU/1/11/740/001	Gel	L01XD04	19.12.2011

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
14.12.2011	Levetiracetam SUN	Levetiracetam	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/741/001	Koncentrat za raztopino za infundiranje	N03AX14	19.12.2011
22.12.2011	Repaglinide Accord	repaglinid	Accord Healthcare Limited Sage house, 319 Pinner road, Harrow, HA1 4HF United Kingdom	EU/1/11/743/001-015	Tableta	A10BX02	28.12.2011
22.12.2011	Topotecan Eagle	topotecan	Eagle Laboratories Limited The Clock House, Station Approach, Marlow, Bucks SL7 1NT, UNITED KINGDOM	EU/1/11/744/001-002	Koncentrat za raztopino za infundiranje	L01XX17	29.12.2011

— **Sprememba dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Odobrena**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
3.11.2011	Clopidogrel Krka	KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556/001-011	7.11.2011
3.11.2011	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Deutschland	EU/1/09/555/001-009	7.11.2011
3.11.2011	Ozurdex	Allergan Pharmaceuticals (Ireland) Ltd, Castlebar Road, Westport, Co. Mayo, Ireland	EU/1/10/638/001	7.11.2011
3.11.2011	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, B-1330 Rixensart, Belgique	EU/1/08/452/001	7.11.2011
3.11.2011	Protaphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/234/010-012	7.11.2011
3.11.2011	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-004	7.11.2011
10.11.2011	Actraphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/229/030-032	15.11.2011
10.11.2011	Actrapid	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/230/010-012	15.11.2011
10.11.2011	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118/001-010	15.11.2011
10.11.2011	Avamys	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/434/001-003	15.11.2011
10.11.2011	Clopidogrel Mylan	Mylan S.A.S 117 allée des Parcs, 69 800 Saint Priest, France	EU/1/09/559/001-016	15.11.2011
10.11.2011	Clopidogrel Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/540/001-016	15.11.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
10.11.2011	Clopidogrel Zentiva	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/08/465/001-020	15.11.2011
10.11.2011	Conbriza	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/511/001-005	15.11.2011
10.11.2011	Cyanokit	Merck Santé s.a.s. 37, rue Saint-Romain, 69379 Lyon Cedex 08, France	EU/1/07/420/001-002	15.11.2011
10.11.2011	ellaOne	Laboratoire HRA Pharma 15, rue Béranger, 75003 Paris, France	EU/1/09/522/001	15.11.2011
10.11.2011	Helixate NexGen	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/00/144/001-005	15.11.2011
10.11.2011	Javlor	Pierre Fabre Médicament 45, place Abel Gance, F-92100 Boulogne, France	EU/1/09/550/001-012	15.11.2011
10.11.2011	Kogenate Bayer	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/143/004-013	15.11.2011
10.11.2011	Levitra	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/03/248/001-023	15.11.2011
10.11.2011	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	15.11.2011
10.11.2011	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423/001-003	15.11.2011
10.11.2011	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/025	15.11.2011
10.11.2011	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	15.11.2011
10.11.2011	Zebinix	BIAL - Portela & Ca, SA A Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado – Portugal	EU/1/09/514/001-020	15.11.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
10.11.2011	Zevalin	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/03/264/001	15.11.2011
10.11.2011	Zoely	Merck Serono Europe Limited 56 Marsh Wall, London E14 9TP, United Kingdom	EU/1/11/690/001-002	15.11.2011
10.11.2011	Zomarist	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/483/001-018	15.11.2011
10.11.2011	Zylagren	KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/558/001-010	16.11.2011
16.11.2011	Exelon	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/066/013 EU/1/98/066/018	18.11.2011
16.11.2011	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-008 EU/1/06/357/018-021	18.11.2011
16.11.2011	Vivanza	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/03/249/001-015	18.11.2011
21.11.2011	Adrovance	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/364/001-004 EU/1/06/364/006-008	23.11.2011
21.11.2011	Aldurazyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/253/001-003	23.11.2011
21.11.2011	Celsentri	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/418/001-010	23.11.2011
21.11.2011	Champix	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/360/001-013	23.11.2011

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21.11.2011	Copalia	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/372/001-039	22.11.2011
21.11.2011	Dafiro	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/371/001-039	22.11.2011
21.11.2011	Evoltra	Genzyme Europe BV Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/06/334/001-005	23.11.2011
21.11.2011	Firdapse	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/09/601/001	23.11.2011
21.11.2011	Inovelon	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/06/378/001-017	23.11.2011
21.11.2011	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/06/368/001-168	23.11.2011
21.11.2011	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436/001-002	23.11.2011
21.11.2011	Rilonacept Regeneron	Regeneron UK Limited 40 Bank Street, E14 5DS London, United Kingdom	EU/1/09/582/001	23.11.2011
21.11.2011	Tygacil	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/06/336/001	23.11.2011
22.11.2011	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/07/387/001-026	24.11.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
22.11.2011	Afinitor	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538/001-008	24.11.2011
22.11.2011	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430/001-002	24.11.2011
22.11.2011	Dynastat	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/209/001-008	24.11.2011
22.11.2011	Effentora	Cephalon Europe 5 Rue Charles Martigny, Maisons-Alfort 94700, France	EU/1/08/441/001-010	24.11.2011
22.11.2011	Exforge	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/370/001-039	24.11.2011
22.11.2011	Fabrazyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/01/188/001-006	25.11.2011
22.11.2011	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535/001-016	24.11.2011
22.11.2011	Imprida	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/373/001-039	24.11.2011
22.11.2011	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026/001-002	24.11.2011
22.11.2011	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278/001-016	24.11.2011
22.11.2011	Lyrica	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/04/279/001-044	24.11.2011

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22.11.2011	Myozyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/06/333/001-003	24.11.2011
22.11.2011	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	24.11.2011
22.11.2011	Onglyza	Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/09/545/001-015	24.11.2011
22.11.2011	Optaflu	Novartis Vaccines and Diagnostics GmbH Emil-von-Behring-Strasse 76, D-35041 Marburg, Deutschland	EU/1/07/394/001-009	24.11.2011
22.11.2011	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmith Kline Biologicals	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/578/001	24.11.2011
22.11.2011	PecFent	Archimedes Development Ltd Nottingham, NGT7 2TN, United Kingdom	EU/1/10/644/001-006	24.11.2011
22.11.2011	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, B-1330 Rixensart, Belgique	EU/1/08/453/002	24.11.2011
22.11.2011	Rasilez	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	24.11.2011
22.11.2011	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267/001-006 EU/1/03/267/008-010	24.11.2011
22.11.2011	Riprazo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-040	24.11.2011

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22.11.2011	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	24.11.2011
22.11.2011	Sprimeo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-040	24.11.2011
22.11.2011	Tasigna	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/422/001-012	24.11.2011
22.11.2011	Thalidomide Celgene	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom	EU/1/08/443/001	24.11.2011
22.11.2011	Trisenox	Cephalon Europe 5 Rue Charles Martigny, 94700 Maisons Alfort, Cedex, France	EU/1/02/204/001	24.11.2011
22.11.2011	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	25.11.2011
24.11.2011	Adenuric	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	EU/1/08/447/001-012	29.11.2011
24.11.2011	Atriance	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/403/001	1.12.2011
24.11.2011	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	30.11.2011
24.11.2011	Clopidogrel HCS	HCS bvba H. Kennisstraat 53, B 2650 Edegem, België	EU/1/10/651/001-015	29.11.2011
24.11.2011	Clopidogrel Teva Generics B.V.	Teva Generics B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/650/001-015	29.11.2011

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24.11.2011	Eucreas	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/425/001-018	28.11.2011
24.11.2011	Galvus	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/414/001-010 EU/1/07/414/018	29.11.2011
24.11.2011	Icandra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/484/001-018	30.11.2011
24.11.2011	Intelence	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse – België	EU/1/08/468/001-002	29.11.2011
24.11.2011	Jalra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485/001-011	29.11.2011
24.11.2011	ReFacto AF	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/103/001-008	29.11.2011
24.11.2011	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	29.11.2011
24.11.2011	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/08/470/001-017	29.11.2011
24.11.2011	Xiliarx	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/486/001-011	29.11.2011
24.11.2011	Zomarist	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/483/001-018	29.11.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
24.11.2011	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/479/001-003	28.11.2011
24.11.2011	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/1/96/022/009-012 EU/1/96/022/014 EU/1/96/022/016-017 EU/1/96/022/019-040	28.11.2011
24.11.2011	Zyprexa Velotab	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/99/125/001-020	28.11.2011
28.11.2011	Emend	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262/001-010	30.11.2011
28.11.2011	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	1.12.2011
28.11.2011	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-005	30.11.2011
28.11.2011	Zutectra	Biotest Pharma GmbH Landsteinerstr.5, 63303 Dreieich, Deutschland	EU/1/09/600/001	30.11.2011
28.11.2011	Zyllt	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553/001-010	30.11.2011
5.12.2011	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185/001-022 EU/1/01/185/031-111	7.12.2011
5.12.2011	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419/001-012	7.12.2011
5.12.2011	Clopidogrel Acino	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/532/001-007	7.12.2011
5.12.2011	Clopidogrel Hexal	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/534/001-007	7.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
5.12.2011	Controloc Control	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/515/001-004	7.12.2011
5.12.2011	Pantozol Control	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/517/001-004	7.12.2011
5.12.2011	Somac Control	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/516/001-004	7.12.2011
5.12.2011	Xenical	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/071/001-006	7.12.2011
7.12.2011	Clopidogrel Teva Pharma	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/561/001-011	9.12.2011
7.12.2011	Pantecta Control	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/518/001-004	9.12.2011
7.12.2011	Pantoloc Control	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/519/001-004	9.12.2011
7.12.2011	Prometax	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/092/013 EU/1/98/092/018-026	12.12.2011
7.12.2011	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/424/001	9.12.2011
8.12.2011	Ceplene	EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland	EU/1/08/477/001	12.12.2011
9.12.2011	Rasilamlo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/686/001-056	13.12.2011
9.12.2011	Xarelto	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/08/472/001-021	20.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
9.12.2011	Zeffix	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/99/114/003	13.12.2011
14.12.2011	Clopidogrel ratiopharm	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/554/001-008	19.12.2011
14.12.2011	Emselex	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/04/294/001-028	19.12.2011
14.12.2011	GILENYA	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/677/001-005	20.12.2011
14.12.2011	Glivec	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/198/001-013	19.12.2011
14.12.2011	Insulatard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/233/010-012	21.12.2011
14.12.2011	Lucentis	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/374/001	19.12.2011
14.12.2011	Mabthera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/067/001-002	19.12.2011
14.12.2011	Pegasys	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/221/001-016	19.12.2011
14.12.2011	Simulect	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/084/001-002	19.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
14.12.2011	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	19.12.2011
14.12.2011	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	19.12.2011
14.12.2011	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	19.12.2011
19.12.2011	Advate	Baxter AG Industriesstrasse 67, 1221 Vienna, Österreich	EU/1/03/271/001-010	21.12.2011
19.12.2011	APTIVUS	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/05/315/001-002	21.12.2011
19.12.2011	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	21.12.2011
19.12.2011	Clopidogrel Acino Pharma GmbH	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/548/001-007	21.12.2011
19.12.2011	Emend	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262/001-008	21.12.2011
19.12.2011	Exjade	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/356/001-009	21.12.2011
19.12.2011	Fendrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, B-1330 Rixensart, Belgique	EU/1/04/299/001-003	21.12.2011
19.12.2011	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-008 EU/1/06/357/018-021	21.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
19.12.2011	Herceptin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/145/001	21.12.2011
19.12.2011	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/03/256/001-010	21.12.2011
19.12.2011	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, BT51 3 RP Northern Ireland	EU/1/03/270/001-005	21.12.2011
19.12.2011	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278/001-016	21.12.2011
19.12.2011	Noxafil	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/320/001	21.12.2011
19.12.2011	Pandemic influenza vaccine H5N1 BAXTER	Baxter AG Industriestraße 67, A - 1221 Wien, Österreich	EU/1/09/571/001	21.12.2011
19.12.2011	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, B-1330 Rixensart, Belgique	EU/1/08/452/001	21.12.2011
19.12.2011	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	21.12.2011
19.12.2011	Somavert	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/240/001-004	21.12.2011
19.12.2011	Synagis	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/99/117/001-002	21.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
19.12.2011	Tasigna	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/422/001-012	21.12.2011
19.12.2011	Tesavel	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435/001-018	21.12.2011
19.12.2011	Tracleer	Actelion Registration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220/001-006	21.12.2011
22.12.2011	Actos	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/00/150/001-030	29.12.2011
22.12.2011	Actos	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/00/150/001-030	29.12.2011
22.12.2011	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, B-1330 Rixensart, Belgique	EU/1/02/224/001-005	27.12.2011
22.12.2011	Arzerra	Glaxo Group Ltd Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/625/001 EU/1/10/625/003	28.12.2011
22.12.2011	Competact	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/06/354/001-012	29.12.2011
22.12.2011	Competact	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/06/354/001-012	3.1.2012
22.12.2011	Glubrava	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/07/421/001-009	29.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
22.12.2011	Glubrava	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/07/421/001-009	29.12.2011
22.12.2011	Glustin	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/00/151/001-024	29.12.2011
22.12.2011	Glustin	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/00/151/001-024	29.12.2011
22.12.2011	Invanz	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/02/216/001-002	3.1.2012
22.12.2011	Ivemend	Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/437/001-004	3.1.2012
22.12.2011	Januvia	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383/001-018	5.1.2012
22.12.2011	Multaq	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/09/591/001-004	28.12.2011
22.12.2011	Multaq	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/09/591/001-004	29.12.2011
22.12.2011	Nevanac	Alcon Laboratories (UK) Ltd. Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/07/433/001	3.1.2012
22.12.2011	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	28.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
22.12.2011	Onglyza	Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/09/545/001-015	3.1.2012
22.12.2011	Ozurdex	Allergan Pharmaceuticals Ireland Castlebar Road, Westport, Co. Mayo, Ireland	EU/1/10/638/001	4.1.2012
22.12.2011	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmith Kline Biologicals	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/578/001	27.12.2011
22.12.2011	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, B-1330 Rixensart, Belgique	EU/1/08/453/002	27.12.2011
22.12.2011	Renagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/99/123/005-013	27.12.2011
22.12.2011	Renvela	Genzyme Europe B.V. Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/09/521/001-007	27.12.2011
22.12.2011	Ristaben	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621/001-018	3.1.2012
22.12.2011	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd. 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/06/366/005-022	29.12.2011
22.12.2011	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd. 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/06/366/005-022	28.12.2011
22.12.2011	Vidaza	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/08/488/001	28.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
22.12.2011	Xelevia	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382/001-018	3.1.2012
22.12.2011	Zavesca	Actelion Registration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/238/001	28.12.2011

— **Ukinitev dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta)**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
28.11.2011	Xigris	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/02/225/001-002	30.11.2011

— **Umik dovoljenja za promet (člen 20 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta)**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
24.11.2011	Busilvex	Pierre Fabre Médicament 45, Place Abel Gance, 92654 Boulogne Billancourt Cedex, France	EU/1/03/254/002	28.11.2011
24.11.2011	Caelyx	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/96/011/001-004	28.11.2011
24.11.2011	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	28.11.2011
24.11.2011	Vidaza	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/08/488/001	25.11.2011
7.12.2011	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416/001-002	9.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
7.12.2011	Luminity	Lantheus MI UK Limited Festival House - 39 Oxford Street - Newbury - Berkshire RG14 1JG – United Kingdom	EU/1/06/361/001-002	12.12.2011
12.12.2011	Vistide	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/97/037/001	14.12.2011

— **Izdaja dovoljenja za promet (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta** [1]**): Odobrena**

Datum sprejetja sklepa	Ime zdravila	INN (mednarodno nelastniško ime)	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Farmacevtska oblika	ATC (anatomsko terapevtska kemijska oznaka)	Datum obvestila
9.12.2011	Inflacam	Meloksikam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, IRELAND	EU/2/11/134/001-014	Oralna suspenzija Rztopina za injiciranje Žvečljive tablete	QM01AC06	13.12.2011
9.12.2011	Panacur AquaSol	Fenbendazol	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/135/001-003	Oralna suspenzija	QP52AC13	13.12.2011
14.12.2011	TruScient	Dibotermin alfa	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/11/136/001	Komplet za implantacijo	QM05BC01	19.12.2011

[1] UL L 136, 30.4.2004, str. 1.

— **Sprememba dovoljenja za promet (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Odobrena**

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
10.11.2011	ProMeris	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/06/064/001-004	15.11.2011
10.11.2011	ProMeris Duo	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/06/065/001-010	15.11.2011
10.11.2011	Zulvac 8 Bovis	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/09/105/001-002	15.11.2011
10.11.2011	Zulvac 8 Ovis	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/09/104/001-002	15.11.2011
16.11.2011	Prac-Tic	Novartis Sanidad Animal S.L. Calle de la Marina, 206, E - Barcelona 08013, ESPANA	EU/2/06/066/001-012	18.11.2011
24.11.2011	Coxevac	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/10/110/001-002	29.11.2011
24.11.2011	Ingelvac CircoFLEX	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/07/079/001-008	29.11.2011
28.11.2011	Melosus	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, D-31303 Burgdorf, Deutschland	EU/2/10/116/004-006	30.11.2011
5.12.2011	Porcilis Porcoli	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/96/001/001-010	7.12.2011
9.12.2011	Masivet	AB Science S.A. 3 avenue George V, 75008 Paris, France	EU/2/08/087/001-002	13.12.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
9.12.2011	Zulvac 1 Ovis	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/11/131/001-006	13.12.2011
14.12.2011	Trocoxil	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/08/084/001-005	19.12.2011
14.12.2011	Zulvac 1 Bovis	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/11/130/001-003	19.12.2011
19.12.2011	Meloxidyl	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/06/070/001-008	21.12.2011
19.12.2011	Ypozane	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros – France	EU/2/06/068/001-004	21.12.2011

Kdor želi dobiti vpogled v javno poročilo o oceni zadevnih zdravil ter o zadevnih sklepih o zdravilih, se lahko obrne na naslov:

The European Medicines Agency
7, Westferry Circus,
Canary Wharf
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