

IV

*(Informacije)*INFORMACIJE INSTITUCIJ, ORGANOV, URADOV IN AGENCIJ EVROPSKE
UNIJE

EVROPSKA KOMISIJA

**Povzetek sklepov Evropske unije o dovoljenjih za promet z zdravili od 1. september 2011 do
31. oktober 2011***(Objavljeno v skladu s členom 13 ali členom 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta ⁽¹⁾)**(2011/C 383/01)*

⁽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
2.9.2011	Vibativ	telavancin	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/11/705/001-002	Prašek za koncentrat za raztopino za infundiranje	J01XA03	6.9.2011
2.9.2011	Votubia	Everolimus	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/710/001-007	Tableta	L01XE10	6.9.2011
5.9.2011	Zytiga	abirateron	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/714/001	Tableta	L02BX03	7.9.2011
16.9.2011	Dexdor	deksmedetomidin	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/11/718/001-006	Koncentrat za raztopino za infundiranje	N05CM18	21.9.2011
19.9.2011	Incivo	telaprevir	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720/001	Filmsko obložene tablete	Pending	22.9.2011
30.9.2011	Pramipexole Accord	pramipeksol	Accord Healthcare Limited 5th Floor Charles House, 108/110 Finchley road, London NW3 5JJ, United Kingdom	EU/1/11/728/001-010	Tableta	N04BC05	4.10.2011
3.10.2011	Levetiracetam Accord	Levetiracetam	Accord Healthcare Limited 5th Floor Charles House, 108/110 Finchley road, London NW3 5JJ, United Kingdom	EU/1/11/712/001-028	Filmsko obložene tablete	N03AX14	5.1.2011
3.10.2011	Levetiracetam Actavis	Levetiracetam	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/713/001-040	Filmsko obložene tablete	N03AX14	5.10.2011

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
3.10.2011	Matever	Levetiracetam	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/11/711/001-030	Filmsko obložene tablete Koncentrat za raztopino za infundiranje	N03AX14	6.10.2011
3.10.2011	Telmisartan Teva Pharma	telmisartan	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/719/001-060	Tableta	C09CA07	5.10.2011
27.10.2011	Eurartesim	dihydroartemisinin / piperakintetrafosfat	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A Viale Shakespeare 47, 00144 Rome, Italia	EU/1/11/716/001-005	Filmsko obložene tablete	P01BF05	2.11.2011

— 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
2.9.2011	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/086/001-034	6.9.2011
2.9.2011	Lucentis	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/374/001	6.9.2011
2.9.2011	Torisel	Wyeth Europa Ltd Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH, United Kingdom	EU/1/07/424/001	6.9.2011
5.9.2011	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/07/387/001-026	7.9.2011
5.9.2011	Aflunov	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/658/001-002	7.9.2011
5.9.2011	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285/001-036	7.9.2011
5.9.2011	Cayston	Gilead Sciences International Limited Granta Park, Abington, Cambridge CB21 6GT, United Kingdom	EU/1/09/543/001-002	7.9.2011
5.9.2011	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030/028-195	7.9.2011
5.9.2011	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	7.9.2011
5.9.2011	Removab	Fresenius Biotech GmbH Am Haag 6-7, D-82166 Graefelfing, Deutschland	EU/1/09/512/001-002	7.9.2011
5.9.2011	Simponi	Janssen Biologics B.V. Einsteinweg 101, CB Leiden 2333, Nederland	EU/1/09/546/001-004	7.9.2011
5.9.2011	Viracept	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/97/054/001 EU/1/97/054/004-005	7.9.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
7.9.2011	CANCIDAS	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/01/196/001 EU/1/01/196/003	9.9.2011
7.9.2011	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square, The Forbury, Reading, Berkshire RG1 3EB, United Kingdom	EU/1/07/392/003	13.9.2011
7.9.2011	Irbesartan HCT Winthrop	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/06/377/001-028	9.9.2011
13.9.2011	Ammonaps	Swedish Orphan Biovitrum International AB SE-11276 Stockholm, Sverige	EU/1/99/120/003-004	15.9.2011
13.9.2011	Luminity	Lantheus MI UK Limited Festival House - 39 Oxford Street - Newbury - Berkshire RG14 1JG - United Kingdom	EU/1/06/361/001-002	15.9.2011
13.9.2011	Raloxifene Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/627/001-003	15.9.2011
13.9.2011	Synagis	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/99/117/001-002	15.9.2011
13.9.2011	Xelevia	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382/001-018	15.9.2011
13.9.2011	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/479/001-003	16.9.2011
16.9.2011	Aerius	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/160/001-013 EU/1/00/160/022-034 EU/1/00/160/036-069	21.9.2011
16.9.2011	Angiox	The Medicines Company UK Ltd 115 L Milton Park, Abingdon, Oxfordshire, OX14 4SA, United Kingdom	EU/1/04/289/001	20.9.2011

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16.9.2011	Azomyr	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/157/001-013 EU/1/00/157/022-067	21.9.2011
16.9.2011	Azopt	Alcon Laboratories (UK) Ltd. Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/00/129/001-003	20.9.2011
16.9.2011	Ilaris	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/564/001-003	20.9.2011
16.9.2011	Myclausen	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, 14167 Berlin, Deutschland	EU/1/10/647/001-004	20.9.2011
16.9.2011	Neoclarityn	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/161/001-013 EU/1/00/161/022-067	21.9.2011
16.9.2011	NeuroBloc	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/00/166/001-003	20.9.2011
16.9.2011	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/08/452/001	21.9.2011
16.9.2011	Resolor	Shire-Movetis NV Veerdijk 58 (1004), B-2300 Turnhout, Belgium	EU/1/09/581/001-008	21.9.2011
16.9.2011	Suboxone	RB Pharmaceuticals Limited 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom	EU/1/06/359/001-004	20.9.2011
16.9.2011	Viramune	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/97/055/001-009	26.9.2011
19.9.2011	Byetta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/06/362/001-004	22.9.2011

Datum sprejetja sklepa	Ime zdravila	Imetnik dovoljenja za promet	Registracijska številka v registru Skupnosti	Datum obvestila
19.9.2011	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/07/384/001-005	22.9.2011
19.9.2011	Ifirmasta	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/480/001-018	22.9.2011
19.9.2011	Temomedac	medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstrasse 3, D-20354 Hamburg – Deutschland	EU/1/09/605/001-012	22.9.2011
19.9.2011	Zonegran	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/04/307/001-021	22.9.2011
22.9.2011	Clopidogrel DURA	Mylan dura GmbH Wittichstraße 6, D-64295 Darmstadt, Deutschland	EU/1/09/560/001-009	26.9.2011
22.9.2011	Ixiaro	Intercell AG Campus Vienna Biocenter 3 A-1030 Wien, Österreich	EU/1/08/501/001-002	26.9.2011
22.9.2011	Leflunomide ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/10/654/001-004	26.9.2011
22.9.2011	Pergoveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/07/396/001-003	26.9.2011
22.9.2011	RoActemra	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	26.9.2011
22.9.2011	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/95/002/001-005	27.9.2011
30.9.2011	Aerinaze	SP Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/07/399/001-006	4.10.2011
3.10.2011	Elaprase	Shire Human Genetic Therapies AB Svärdvägen 11D, 18233 Danderyd, Sverige	EU/1/06/365/001-003	5.10.2011

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3.10.2011	Lysodren	Laboratoire HRA Pharma 15, rue Béranger, 75003 Paris, France	EU/1/04/273/001	5.10.2011
3.10.2011	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/363/001-015	5.10.2011
3.10.2011	Xagrid	Shire Pharmaceutical Contracts Ltd Hampshire International Business Park, Chineham, Basingstoke, Hampshire RG24 8EP, United Kingdom	EU/1/04/295/001	5.10.2011
6.10.2011	NeoRecormon	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/97/031/001-046	10.10.2011
6.10.2011	Noxafil	SP Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/05/320/001	10.10.2011
6.10.2011	Sildenafil Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/09/595/001-015	10.10.2011
6.10.2011	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110/001-005 EU/1/99/110/008-010	10.10.2011
6.10.2011	Topotecan Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633/001-002	10.10.2011
12.10.2011	Celsentri	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/418/001-010	13.10.2011
12.10.2011	Galvus	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/414/001-010 EU/1/07/414/018	14.10.2011
12.10.2011	Invega	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/07/395/001-095	14.10.2011

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12.10.2011	Jalra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485/001-011	14.10.2011
12.10.2011	Rilonacept Regeneron	Regeneron UK Limited 40 Bank Street, London, E14 5DS United Kingdom	EU/1/09/582/001	14.10.2011
12.10.2011	Stelara	Janssen-Cilag International NV Turnhousweg, 30 - 2340 Beerse - België	EU/1/08/494/001-004	14.10.2011
12.10.2011	Teysuno	Taiho Pharma Europe, Limited 55 Colmore Row, Birmingham, West Midlands, B3 2AS, United Kingdom	EU/1/11/669/001-004	14.1.2011
12.10.2011	Xeplion	Janssen-Cilag International NV Turnhousweg 30, B-2340 Beerse, België	EU/1/11/672/001-006	14.10.2011
12.10.2011	Xiliarx	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/486/001-011	14.10.2011
17.10.2011	Docetaxel Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/611/001-002	19.10.2011
20.10.2011	Arixtra	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/02/206/001-035	24.10.2011
20.10.2011	Karvezide	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/98/085/001-034	24.10.2011
20.10.2011	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/008-013 EU/1/07/400/017-024	24.10.2011
20.10.2011	Naglazyme	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/05/324/001-002	24.10.2011
20.10.2011	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/479/001-003	24.10.2011

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20.10.2011	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	28.9.2011
20.10.2011	Zyprexa Velotab	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/99/125/001-020	28.9.2011
24.10.2011	Alimta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/290/001-002	26.10.2011
24.10.2011	Avonex	Biogen Idec Ltd Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/97/033/002-006	26.10.2011
24.10.2011	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/086/001-034	26.10.2011
24.10.2011	Daxas	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/10/636/001-007	26.10.2011
24.10.2011	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/07/384/001-005	26.10.2011
24.10.2011	Ebixa	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/02/219/001-049	26.10.2011
24.10.2011	Efient	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/08/503/001-016	26.10.2011
24.10.2011	Emend	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262/001-008	27.10.2011
24.10.2011	Erbixux	Merck KGaA Frankfurter Straße 250, 64271 Darmstadt, Deutschland	EU/1/04/281/001-005	26.10.2011
24.10.2011	Humira	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/03/256/001-010	26.10.2011

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24.10.2011	Icandra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/484/001-018	26.10.2011
24.10.2011	IntronA	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/99/127/011-039 EU/1/99/127/041-044	27.10.2011
24.10.2011	Irbesartan HCT Winthrop	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/06/377/001-028	26.10.2011
24.10.2011	Keppra	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef, 60, Brussel 1070, België	EU/1/00/146/001-032	26.10.2011
24.10.2011	Kivexa	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/04/298/001-003	26.10.2011
24.10.2011	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278/001-016	26.10.2011
24.10.2011	Lyrica	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 139NJ, United Kingdom	EU/1/04/279/001-044	26.10.2011
24.10.2011	Nexavar	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/06/342/001	26.10.2011
24.10.2011	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	26.10.2011
24.10.2011	Prevenar 13	Wyeth-Lederle Vaccines S.A. Pleinlaan 17 Boulevard de la Plaine, 1050 Brussels - Bruxelles, Belgie-Belgique	EU/1/09/590/001-006	26.10.2011
24.10.2011	Revatio	Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/05/318/001	26.10.2011

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24.10.2011	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/05/330/001-011	26.10.2011
24.10.2011	Starlix	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/174/001-021	26.10.2011
24.10.2011	Sycrest	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640/001-006	26.10.2011
24.10.2011	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386/001-018	26.10.2011
24.10.2011	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	26.10.2011
24.10.2011	Ziagen	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/99/112/001-002	26.10.2011
27.10.2011	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/07/387/001-026	4.11.2011
27.10.2011	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstr. 100, D-60318 Frankfurt/Main – Deutschland	EU/1/02/218/001-003 EU/1/02/218/005-030	4.11.2011
27.10.2011	Ceprothin	Baxter AG Industriestraße 67, A - 1221 Wien, Österreich	EU/1/01/190/001-002	4.11.2011
27.10.2011	Eucreas	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/425/001-018	4.11.2011
27.10.2011	Exalief	BIAL - Portela & Ca, SA A Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado – Portugal	EU/1/09/520/001-020	4.11.2011
27.10.2011	Galvus	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/414/001-010 EU/1/07/414/018	4.11.2011

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27.10.2011	Jalra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485/001-011	4.11.2011
27.10.2011	Leflunomide Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/09/604/001-010	1.11.2011
27.10.2011	Mixtard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/231/030-032	1.11.2011
27.10.2011	Rapiscan	Rapidscan Pharma Solutions EU Ltd. Regent's Place, 338 Euston Road, London NW1 3BT, UK	EU/1/10/643/001	4.11.2011
27.10.2011	Rasilamlo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/686/001-056	4.11.2011
27.10.2011	Riprazo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-040	1.11.2011
27.10.2011	Riprazo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/680/001-080	4.11.2011
27.10.2011	Sprimeo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-040	1.11.2011
27.10.2011	Sprimeo HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/683/001-080	4.11.2011
27.10.2011	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/95/002/001-005	4.11.2011
27.10.2011	Tygacil	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/06/336/001	4.11.2011
27.10.2011	Xiliarx	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/486/001-011	4.11.2011

— **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
3.10.2011	Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/478/001	5.10.2011
17.10.2011	Ablavar	TMC Pharma Services Ltd. Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, Hampshire, RG27 8AS, United Kingdom	EU/1/05/313/001-009	19.10.2011

— 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
7.9.2011	Nobivac Myxo-RHD	Miksoma virus, živi vektorski RHD sev 009	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/132/001-004	Liofilizat in topilo - vbrizgljiva suspenzija	QI08AD	9.9.2011
13.9.2011	Recocam	Meloksikam	CF Pharma Limited Unit 622, Northern Extension, Waterford, Ireland	EU/2/11/133/001-003	Rztopina za injiciranje	QM01AC06	15.9.2011
6.10.2011	Recuvyra	Fentanil	Nexcyon Pharmaceuticals Ltd. Bank Barn, How Mill, Brampton, Cumbria CA8 9JY, UNITED KINGDOM	EU/2/11/127/001	transdermalna raztopina	QN02AB03	11.10.2011

⁽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
5.9.2011	Improvac	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/09/095/001-006	7.9.2011
13.9.2011	Cortavance	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France	EU/2/06/069/001	15.9.2011
16.9.2011	Loxicom	Norbrook Laboratories Limited Station Works, Newry, Co. Down, BT35 6JP, United Kingdom	EU/2/08/090/001-026	20.9.2011
16.9.2011	Porcilis Pesti	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/99/016/001-006	21.9.2011
19.9.2011	ZULVAC 1 + 8 Ovis	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/11/120/001-003	22.9.2011
20.10.2011	Suprelorin	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France	EU/2/07/072/003-004	24.10.2011
24.10.2011	Meloxoral	Le Vet B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/10/111/001-007	26.10.2011

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

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