IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2011 to 31 December 2011

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council [1]*)*

(2012/C 56/01)

[1] OJ L 136, 30.4.2004, p. 1.

— **Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
3.11.2011	Plenadren	hydrocortisone	DuoCort Pharma AB Kullagatan 8-10, S-252 20 Helsingborg, Sveridge	EU/1/11/715/001-002	Modified-release tablet	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	Film-coated tablet	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	Capsule, soft	N07XX08	18.11.2011
22.11.2011	Rasitrio	aliskiren / amlodipine / hydrochlorothiazide	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/730/001-060	Film-coated tablet	C09XA54	24.11.2011
24.11.2011	Desloratadine Teva	desloratadine	Teva Pharma B.V Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/732/001-013	Film-coated tablet	R06AX27	29.11.2011
24.11.2011	Komboglyze	saxagliptin / 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	Film-coated tablet	A10BD	28.11.2011
24.11.2011	Onduarp	telmisartan / amlodipine	Boehringer Ingelheim International GmbH Binger Str. 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729/001-006	Tablet	C09DB04	28.11.2011

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
28.11.2011	Dasselta	desloratadine	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/739/001-008	Film-coated tablet	R06AX27	30.11.2011
28.11.2011	EDURANT	rilpivirine	Janssen Cilag International NV Turnhoutseweg 30, B 2340 Beerse, België	EU/1/11/736/001	Film-coated tablet	J05AG05	30.11.2011
28.11.2011	Eviplera	emtricitabine / rilpivirine (as hydrochloride) / tenofovir disoproxil (as fumarate)	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/11/737/001-002	Film-coated tablet	J05AR08	28.11.2011
5.12.2011	Dificlir	fidaxomicin	FGK Representative Service GmbH Heimeranstrasse 35, 80339 München, Deutschland	EU/1/11/733/001-004	Film-coated tablet	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	Oral solution	N03AX14	7.12.2011
7.12.2011	Edarbi	azilsartan medoxomil	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/11/734/001-011	Tablet	C09CA09	9.12.2011
7.12.2011	Ipreziv	azilsartan medoxomil	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/11/735/001-011	Tablet	C09CA09	9.12.2011
14.12.2011	Ameluz	5-Aminolaevulinic acid	Biofrontera Bioscience GmbH Hemmelrather Weg 201, 51377 Leverkusen, Deutschland	EU/1/11/740/001	Gel	L01XD04	19.12.2011

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
14.12.2011	Levetiracetam SUN	levetiracetam	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/741/001	Concentrate for solution for infusion	N03AX14	19.12.2011
22.12.2011	Repaglinide Accord	Repaglinide	Accord Healthcare Limited Sage house, 319 Pinner road, Harrow, HA1 4HF United Kingdom	EU/1/11/743/001-015	Tablet	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	Concentrate for solution for infusion	L01XX17	29.12.2011

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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, London, E14 5DS 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

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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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

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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

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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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

— **Withdrawal of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

— **Suspension of a marketing authorization (Article 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

— Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council [1]): Accepted

Date of the Décision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
9.12.2011	Inflacam	Meloxicam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, IRELAND	EU/2/11/134/001-014	Chewable tablet Oral suspension Solution for injection	QM01AC06	13.12.2011
9.12.2011	Panacur AquaSol	Fenbendazole	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/135/001-003	Oral suspension	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	Kit for implant	QM05BC01	19.12.2011

[1] OJ L 136, 30.4.2004, p. 1.

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
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

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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