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 July 2011 to 31 August 2011

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

(2011/C 316/01)

[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
13.7.2011	Benlysta	belimumab	Glaxo Group Limited Glaxo Wellcome House, Berkely Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/700/001-002	powder for concentrate for solution for infusion	L04AA26	15.7.2011
13.7.2011	Temozolomide Sun	temozolomide	Sun Pharmaceuticals Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/697/001-012	Capsule, hard	L01AX03	18.7.2011
13.7.2011	Xgeva	denosumab	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/11/703/001-002	Solution for injection	M05BX04	15.7.2011
13.7.2011	Yervoy	ipilimumab	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/698/001-002	Concentrate for solution for infusion	L01XC11	15.7.2011
18.7.2011	Victrelis	boceprevir	Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom	EU/1/11/704/001	Capsule, hard	J05AE	20.7.2011
20.7.2011	Fampyra	fampridine	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/11/699/001-002	Prolonged-release tablet	N07XX07	25.7.2011
20.7.2011	TOBI Podhaler	Tobramycin	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/10/652/001-003	Inhalation powder, hard capsule	J01GB01	25.7.2011
26.7.2011	Ibandronic acid Sandoz	Ibandronic acid	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/11/685/001-005	Film-coated tablet	M05BA06	28.7.2011
27.7.2011	Zoely	nomegestrol/estradiol	Merck Serono Europe Limited 56 Marsh Wall, London E14 9TP, United Kingdom	EU/1/11/690/001-002	Film-coated tablet	G03AA14	1.8.2011

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
18.8.2011	Entacapone Orion	entacapone	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/11/708/001-004	Film-coated tablet	N04BX02	22.8.2011
24.8.2011	Levodopa/Carbidopa/ Entacapone Orion	Levodopa, carbidopa, entacapone	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/11/706/001-033	Film-coated tablet	N04BA03	29.8.2011
24.8.2011	Trajenta	linagliptin	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/11/707/001-011	Film-coated tablet	A10BH05	30.8.2011
26.8.2011	Levetiracetam ratiopharm	levetiracetam	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/11/702/001-031	Film-coated tablet Oral solution	N03AX14	31.8.2011
26.8.2011	Levetiracetam Teva	levetiracetam	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/701/001-028	Film-coated tablet	N03AX14	31.8.2011

— **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
5.7.2011	Irbesartan Winthrop	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/06/376/001-033	7.7.2011
5.7.2011	Relistor	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/08/463/001-011	7.7.2011
7.7.2011	Adrovance	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/364/005 EU/1/06/364/009	11.7.2011
7.7.2011	Ammonaps	Swedish Orphan Biovitrum International AB SE-112 76 Stockholm, Sverige	EU/1/99/120/001-004	12.7.2011
7.7.2011	Hirobriz Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/09/594/001-010	11.7.2011
7.7.2011	Modigraf	Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland	EU/1/09/523/001-002	11.7.2011
7.7.2011	Removab	Fresenius Biotech GmbH Am Haag 6-7, D-82166 Graefelfing, Deutschland	EU/1/09/512/001-002	11.7.2011
11.7.2011	NovoRapid	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/99/119/001 EU/1/99/119/003 EU/1/99/119/005-015 EU/1/99/119/017-023	13.7.2011
11.7.2011	Onbrez Breezhaler	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/593/001-010	13.7.2011
11.7.2011	Optaflu	Novartis Vaccines and Diagnostics GmbH Emil-von-Behring-Strasse 76, D-35041 Marburg, Deutschland	EU/1/07/394/001-009	13.7.2011
13.7.2011	Sildenafil ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/09/603/001-015	18.7.2011
13.7.2011	Stocrin	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111/001-005 EU/1/99/111/008-011	18.7.2011
13.7.2011	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	18.7.2011
13.7.2011	ViraferonPeg	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/132/001-050	18.7.2011

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
13.7.2011	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	18.7.2011
18.7.2011	Crixivan	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/024/001-005 EU/1/96/024/010	20.7.2011
18.7.2011	Intrinsa	Warner Chilcott UK Ltd Old Belfast Road, Millbrook, Larne, County Antrim BT40 2SH, United Kingdom	EU/1/06/352/001-003	20.7.2011
18.7.2011	Livensa	Warner Chilcott Deutschland Gmbh Dr.-Otto-Röhm-Strasse 2-4, Weiterstadt 64331, Deutschland	EU/1/06/351/001-003	20.7.2011
18.7.2011	Multaq	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/09/591/001-004	20.7.2011
18.7.2011	ReFacto AF	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/99/103/001-008	20.7.2011
18.7.2011	Savene	SpePharm Holding BV Kingsfordweg 151, GR Amsterdam 1043, Nederland	EU/1/06/350/001	20.7.2011
20.7.2011	Atriance	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/403/001	25.7.2011
20.7.2011	Betaferon	Bayer Schering Pharma AG Müllerstrasse 170-178, D - 13342 Berlin, Deutschland	EU/1/95/003/003-012	25.7.2011
20.7.2011	Esbriet	InterMune UK Ltd 4th Floor, One Victoria Street, Bristol, BS1 6AA, United Kingdom	EU/1/11/667/001-003	26.7.2011
20.7.2011	Intelence	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/468/001	25.7.2011
20.7.2011	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444/001-012	25.7.2011
20.7.2011	Rivastigmine 1 A Pharma	1 A Pharma GmbH Keltenring 1+3, Oberhaching 82041, Deutschland	EU/1/09/585/001-018	25.7.2011
20.7.2011	Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/09/599/001-018	25.7.2011
20.7.2011	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	25.7.2011

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
20.7.2011	Zalasta	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/07/415/001-056	25.7.2011
26.7.2011	Avaglim	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/06/349/001-010	28.7.2011
26.7.2011	Bondronat	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/012/004 EU/1/96/012/009-013	28.7.2011
26.7.2011	Busilvex	Pierre Fabre Médicament 45, Place Abel Gance, 92654 Boulogne Billancourt Cedex, France	EU/1/03/254/002	28.7.2011
26.7.2011	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/296/001-009	28.7.2011
26.7.2011	Forsteo	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/03/247/001-002	28.7.2011
26.7.2011	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/00/152/001-008 EU/1/00/152/019-020	28.7.2011
26.7.2011	Kuvan	Merck Serono Europe Limited 56 Marsh Wall, London E14 9TP, United Kingdom	EU/1/08/481/001-003	28.7.2011
26.7.2011	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614/001-003	28.7.2011
26.7.2011	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	28.7.2011
26.7.2011	Retacrit	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/07/431/001-025	28.7.2011
26.7.2011	Stelara	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/494/001-004	28.7.2011
26.7.2011	Xeristar	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/297/001-008	28.7.2011
27.7.2011	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	2.8.2011
27.7.2011	Beromun	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/99/097/001	1.8.2011

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27.7.2011	Bondenza	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/266/003-006	29.7.2011
27.7.2011	Bonviva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/265/003-006	29.7.2011
27.7.2011	Copalia	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/372/001-039	1.8.2011
27.7.2011	Dafiro	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/371/001-039	1.8.2011
27.7.2011	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416/001-002	29.7.2011
27.7.2011	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/03/261/001-003	3.8.2011
27.7.2011	Eporatio	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/09/573/001-028	29.7.2011
27.7.2011	Exforge	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/370/001-039	29.7.2011
27.7.2011	Exjade	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/356/001-009	1.8.2011
27.7.2011	Faslodex	AstraZeneca UK Limited Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom	EU/1/03/269/001-002	1.8.2011
27.7.2011	Fosavance	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/310/005 EU/1/05/310/009	29.7.2011
27.7.2011	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-008 EU/1/06/357/018-021	29.7.2011
27.7.2011	Imprida	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/373/001-039	29.7.2011
27.7.2011	Integrilin	Glaxo Group Ltd Greenford, Middlesex, UB6 ONN, United Kingdom	EU/1/99/109/001-002	1.8.2011

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27.7.2011	Kiovig	Baxter AG Industriestraße 67, A - 1221 Wien, Österreich	EU/1/05/329/001-006	29.7.2011
27.7.2011	Leflunomide Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/09/604/001-010	2.8.2011
27.7.2011	Nevanac	Alcon Laboratories (UK) Ltd. Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/07/433/001	29.7.2011
27.7.2011	PhotoBarr	Axcan Pharma International BV Engelenkampstraat 72, 6131 JJ Sittard, Nederland	EU/1/04/272/001-002	2.8.2011
27.7.2011	PREZISTA	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/06/380/001-005	2.8.2011
27.7.2011	Rapamune	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/01/171/001 EU/1/01/171/007-010 EU/1/01/171/013-014	1.8.2011
27.7.2011	Relistor	TMC Pharma Services Ltd. Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, Hampshire, RG27 8AS, United Kingdom	EU/1/08/463/001-011	1.8.2011
27.7.2011	Silgard	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358/001-021	2.8.2011
27.7.2011	Sycrest	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640/001-006	2.8.2011
27.7.2011	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498/001-008	29.7.2011
27.7.2011	Truvada	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/04/305/001-002	3.8.2011
27.7.2011	Valdoxan	Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/08/499/001-008	1.8.2011
27.7.2011	Vantavo	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572/005 EU/1/09/572/009	1.8.2011
27.7.2011	Yentreve	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/280/001-008	29.7.2011
1.8.2011	alli	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/401/007-016	3.8.2011

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1.8.2011	Doribax	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/467/001-002	3.8.2011
1.8.2011	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-021	3.8.2011
1.8.2011	Iressa	AstraZeneca AB Sodertalje S 151 85, Sverige	EU/1/09/526/001-002	3.8.2011
1.8.2011	Nexavar	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/06/342/001	2.8.2011
1.8.2011	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-014	3.8.2011
1.8.2011	Rivastigmine Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/513/001-020	3.8.2011
1.8.2011	RoActemra	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	3.8.2011
5.8.2011	ATryn	GTC Biotherapeutics UK Limited 10 Norwich Street, London EC4A 1BD, United Kingdom	EU/1/06/355/001-003	10.8.2011
5.8.2011	Biograstim	CT Arzneimittel GmbH Lengeder Straße 42a, D-13407 Berlin, Deutschland	EU/1/08/450/001-010	10.8.2011
5.8.2011	Biopoin	CT Arzneimittel GmbH Lengeder Straße 42a, D-13407 Berlin, Deutschland	EU/1/09/565/001-028	10.8.2011
5.8.2011	Enbrel	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/99/126/001-022	10.8.2011
5.8.2011	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/07/385/001-002 EU/1/07/385/004	10.8.2011
5.8.2011	Hepsera	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/03/251/001-002	10.8.2011
5.8.2011	Hycamtin	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/96/027/001 EU/1/96/027/003-007	10.8.2011
5.8.2011	InductOs	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/02/226/001	10.8.2011

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5.8.2011	Silapo	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/07/432/001-022	10.8.2011
5.8.2011	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508/001-010	10.8.2011
5.8.2011	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	10.8.2011
10.8.2011	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118/001-010	12.8.2011
10.8.2011	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268/001-004	12.8.2011
10.8.2011	Filgrastim Hexal	HEXAL AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/08/496/001-016	12.8.2011
10.8.2011	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134/001-037	12.8.2011
10.8.2011	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133/001-032	12.8.2011
10.8.2011	Oslif Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/09/586/001-010	12.8.2011
10.8.2011	Vidaza	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/08/488/001	12.8.2011
10.8.2011	Zarzio	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/08/495/001-016	12.8.2011
18.8.2011	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/283/008-012	22.8.2011
18.8.2011	Karvezide	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/98/085/001-034	22.8.2011
18.8.2011	Osseor	Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/04/287/001-006	22.8.2011
18.8.2011	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/08/452/001	22.8.2011
18.8.2011	Protelos	Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/04/288/001-006	22.8.2011

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18.8.2011	Sutent	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/347/001-008	22.8.2011
18.8.2011	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	22.8.2011
19.8.2011	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430/001-002	23.8.2011
24.8.2011	Afinitor	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538/001-008	30.8.2011
24.8.2011	Efficib	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457/001-016	30.8.2011
24.8.2011	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/126/001-022	9.9.2011
24.8.2011	Intelence	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/468/001	30.8.2011
24.8.2011	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	30.8.2011
24.8.2011	Janumet	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455/001-016	30.8.2011
24.8.2011	Januvia	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383/001-018	30.8.2011
24.8.2011	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, Northern Ireland BT51 3 RP	EU/1/03/270/001-005	30.8.2011
24.8.2011	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134/001-037	30.8.2011
24.8.2011	Mepact	IDM PHARMA SAS 11-15 quai De Dion Bouton, 92816 Puteaux Cedex, France	EU/1/08/502/001	30.8.2011
24.8.2011	Micardis	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090/017-022	29.8.2011
24.8.2011	Modigraf	Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland	EU/1/09/523/001-002	29.8.2011

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
24.8.2011	Multaq	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/09/591/001-004	26.8.2011
24.8.2011	Mycamine	Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland	EU/1/08/448/001-002	26.8.2011
24.8.2011	Neupro	Schwarz Pharma Ltd Shannon, Industrial Estate, Co.Clare, Ireland	EU/1/05/331/001-055	26.8.2011
24.8.2011	Nplate	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/08/497/001-008	30.8.2011
24.8.2011	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133/001-032	29.8.2011
24.8.2011	Osigraft	Howmedica International S. de R.L. Division of Stryker Corporation, Raheen Industrial Estate, Raheen, Limerick, Ireland	EU/1/01/179/001	30.8.2011
24.8.2011	PegIntron	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/131/001-050	26.8.2011
24.8.2011	Pelzont	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/460/001-014	26.8.2011
24.8.2011	Rebetol	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/99/107/001-005	29.8.2011
24.8.2011	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267/001-010	30.8.2011
24.8.2011	Ristaben	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621/001-018	30.8.2011
24.8.2011	Ristfor	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620/001-016	30.8.2011
24.8.2011	Stalevo	Orion Corporation Orionintie 1, FIN-02200 Espoo, Suomi	EU/1/03/260/001-038	30.8.2011
24.8.2011	Starlix	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/174/001-021	30.8.2011

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
24.8.2011	Tarceva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/05/311/001-003	26.8.2011
24.8.2011	Tesavel	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435/001-018	30.8.2011
24.8.2011	Thyrogen	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/99/122/001-002	30.8.2011
24.8.2011	Tredaptive	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/459/001-014	30.8.2011
24.8.2011	Trevaclyn	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/458/001-014	30.8.2011
24.8.2011	Tygacil	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/06/336/001	30.8.2011
24.8.2011	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	30.8.2011
24.8.2011	Velmetia	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456/001-016	30.8.2011
24.8.2011	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	30.8.2011
24.8.2011	ViraferonPeg	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/132/001-050	30.8.2011
24.8.2011	Yttriga	Eckert & Ziegler Nuclitec GmbH Gieselweg 1, Braunschweig 38110, Deutschland	EU/1/05/322/001-002	29.8.2011
24.8.2011	Zevalin	Bayer Schering Pharma AG D-13342 Berlin, Deutschland	EU/1/03/264/001	30.8.2011
24.8.2011	Zometa	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/176/001-009	30.8.2011
26.8.2011	Alisade	Glaxo Group Ltd Greenford, Middlesex, UB6 ONN, United Kingdom	EU/1/08/474/001-003	31.8.2011
26.8.2011	Avamys	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/434/001-003	31.8.2011

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
26.8.2011	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419/001-012	31.8.2011
26.8.2011	Corlentor	Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/05/317/001-014	31.8.2011
26.8.2011	Fertavid	SP Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/09/510/001-019	31.8.2011
26.8.2011	HBVAXPRO	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/01/183/001 EU/1/01/183/004-005 EU/1/01/183/007-008 EU/1/01/183/011 EU/1/01/183/013 EU/1/01/183/015 EU/1/01/183/018-032	31.8.2011
26.8.2011	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/06/368/001-168	31.8.2011
26.8.2011	Procoralan	Les Laboratoires Servier 22, rue Garnier, 92200 Neuilly-sur-Seine, France	EU/1/05/316/001-014	31.8.2011
26.8.2011	Prolia	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	31.8.2011
26.8.2011	Sebivo	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/388/001-003	31.8.2011
26.8.2011	Tepadina	ADIENNE S.r.l. via Broseta, 64/B, 24128 Bergamo, Italia	EU/1/10/622/001-002	31.8.2011
26.8.2011	Topotecan Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/09/552/001-004	31.8.2011

— **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
5.8.2011	Proteq West Nile	West Nile recombinant canarypox virus (vCP2017 virus)	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/11/129/001-004	Suspension for injection	QI05AX	10.8.2011
5.8.2011	Zulvac 1 Bovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP ≥ 1	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/11/130/001-003	Suspension for injection	QI02AA08	10.8.2011
5.8.2011	Zulvac 1 Ovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP ≥ 1	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/11/131/001-006	Suspension for injection	QI04AA02	10.8.2011
18.8.2011	Emdocam	Meloxicam	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/11/128/001-003	Solution for injection	QM01AC06	22.8.2011

[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
7.7.2011	Leucofeligen FeLV/RCP	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros Cedex France	EU/2/09/097/001-002	11.7.2011
7.7.2011	Palladia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/09/100/001-003	12.7.2011
7.7.2011	ProMeris Duo	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/06/065/001-010	11.7.2011
11.7.2011	Trocoxil	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/08/084/001-005	13.7.2011
13.7.2011	Loxicom	Norbrook Laboratories Limited Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090/001-018	18.7.2011
20.7.2011	Posatex	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/08/081/001-003	25.7.2011
27.7.2011	Poulvac FluFend H5N3 RG	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/06/060/001-002	1.8.2011
27.7.2011	ProMeris	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/06/064/001-004	1.8.2011
27.7.2011	Slentrol	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/07/071/001-003	2.8.2011
5.8.2011	Cerenia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/06/062/001-005	10.8.2011
5.8.2011	Virbagen Omega	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France	EU/2/01/030/001-004	10.8.2011
19.8.2011	Nobilis Influenza H5N2	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/06/061/001-004	23.8.2011
19.8.2011	Zolvix	Novartis Healthcare A/S Lyngbyvej 172, DK-2100 Copenhagen, Danmark	EU/2/09/101/001-010	23.8.2011
24.8.2011	Suvaxyn Aujeszky 783 +O/W	Fort Dodge Animal Health Holland C.J. van Houtenlaan 36, 1381 CP Weesp, Nederland	EU/2/98/009/001-006	30.8.2011

— **Withdrawal of a marketing authorization (Article 38 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
10.8.2011	Yarvitan	Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse, België	EU/2/06/063/001-003	12.8.2011

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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UK - LONDON E14 4H