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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 August 2012 to 31 August 2012

(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 371/01)

— **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
30.8.2012	Erbitux	Merck KGaA Frankfurter Straße 250, 64271 Darmstadt, Deutschland	EU/1/04/281/001-005	3.9.2012

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

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 August 2012 to 31 August 2012

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2012/C 371/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
23.8.2012	Zinnat and associated names	See Annex	See Annex	27.8.2012

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	GlaxoSmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 1140 Wien Austria	Flolan 0,5 mg - Trockensubstanz zur Infusionsbereitung mit Lösungsmittel	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Austria	GlaxoSmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 1140 Wien Austria	Flolan 1,5 mg - Trockensubstanz zur Infusionsbereitung mit Lösungsmittel	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/100 ml
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 1332 Genval Belgium	Flolan 0,5 mg powder and solvent for solution for infusion	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 1332 Genval Belgium	Flolan 1,5 mg powder and solvent for solution for infusion	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/100 ml
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 1332 Genval Belgium	Flolan 1,5 mg powder for solution for infusion	1,5 mg	Powder for solution for infusion	Intravenous use	1,5 mg/50 ml
Czech Republic	The Wellcome Foundation Ltd., Berkeley Avenue 21, Greenford, Middlesex, UB6 0NN United Kingdom	Flolan 0,5 mg, powder and solvent for solution for infusion	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Czech Republic	The Wellcome Foundation Ltd., Berkeley Avenue 21, Greenford, Middlesex, UB6 0NN United Kingdom	Flolan 1,5 mg, powder and solvent for solution for infusion	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/50 ml

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Denmark	GlaxoSmithKline Pharma A/S Nykaer 68, 2605 Broendby Denmark	Epoprostenol 500 micrograms	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Denmark	GlaxoSmithKline Pharma A/S Nykaer 68, 2605 Broendby Denmark	Eepoprostenol 1,5 mg	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/50 ml
Estonia	Glaxo Wellcome UK Limited trading as Glaxo Wellcome Operations Glaxo Wellcome House Berkeley Avenue, Greenford Middlesex UB6 0NN United Kingdom	Flolan	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
France	Laboratoire GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	Flolan 0,5 mg, powder and solvent for solution for injection	0,5 mg	Powder and solvent for solution for injection	Intravenous use	0,5 mg/50 ml
France	Laboratoire GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	Flolan 1,5 mg, powder and solvent for solution for injection	1,5 mg	Powder and solvent for solution for injection	Intravenous use	1,5 mg/50 ml
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham, Dublin 16 Ireland	Flolan 500 micrograms Powder and Solvent for Solution for Infusion	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham, Dublin 16 Ireland	Flolan 1,5 mg Infusion, powder and solvent for solution for infusion	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/50 ml

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Italy	The Wellcome Foundation Ltd. Glaxo Wellcome house Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Italy	The Wellcome Foundation Ltd. Glaxo Wellcome house Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan	0,5 mg	Powder for solution for infusion	Intravenous use	0,5 mg/100 ml
Italy	The Wellcome Foundation Ltd. Glaxo Wellcome house Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/50 ml
Luxembourg	GlaxoSmithKline Pharmaceuticals SA 2-4-6, Avenue Pascal B-1330 Wavre Belgium	Flolan 0,5 mg powder and solvent for solution for infusion	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
Luxembourg	GlaxoSmithKline Pharmaceuticals SA 2-4-6, Avenue Pascal B-1330 Wavre Belgium	Flolan 1,5 mg powder and solvent for solution for infusion	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/100 ml
Malta	Glaxo Wellcome UK Limited Glaxo Wellcome House Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan 0,5 mg Injection Powder and solvent for solution for Infusion 0,5 mg	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 500 microgram, powder for solution for infusion	0,5 mg	Powder for solution for infusion	Intravenous use	0,5 mg/50 ml

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 500 microgram, powder and solvent for solution for infusion	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/100 ml
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 1500 microgram, powder for solution for infusion	1,5 mg	Powder for solution for infusion	Intravenous use	1,5 mg/50 ml
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 1500 microgram, powder and solvent for solution for infusion	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/100 ml
Norway	GlaxoSmithKline AS Forskningsveien 2 A Postboks 180 Vinderen 0319 Oslo Norway	Flolan	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/100 ml
Norway	GlaxoSmithKline AS Forskningsveien 2 A Postboks 180 Vinderen 0319 OSLO Norway	Flolan	1,5 mg	Powder and solvent for solution for infusion	Intravenous use	1,5 mg/100 ml
Spain	GlaxoSmithKline, S.A. P.T.M. - C/Severo Ochoa, 2 28760 - Tres Cantos Madrid Spain	Flolan	0,5 mg	Powder and solvent for solution for infusion	Intravenous use	0,5 mg/50 ml
United Kingdom	Glaxo Wellcome UK Ltd Stockley Park West Uxbridge Middlesex, UB11 1BT United Kingdom	Flolan 0,5 mg Injection	0,5 mg	Freeze-Dried Powder	Intravenous use	0,5 mg/50 ml
United Kingdom	Glaxo Wellcome UK Ltd Stockley Park West Uxbridge Middlesex, UB11 1BT United Kingdom	Flolan 1,5 mg Injection	1,5 mg	Sterile freeze-dried powder for solution for infusion	Intravenous use	1,5 mg/50 ml

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 October 2012 to 31 October 2012

(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 371/03)

[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
23.10.2012	XALKORI	crizotinib	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/1/12/793/001-004	Capsule, hard	L01XE16	26.10.2012
25.10.2012	Adcetris	Brentuximab vedotin	Takeda Global Research and Development Centre (Europe) Ltd. 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/12/794/001	powder for concentrate for solution for infusion	L01XC12	30.10.2012
25.10.2012	Glybera	Alipogene tiparvovec	uniQure biopharma B.V. Meibergdreef 61, 1105 BA Amsterdam, Nederland	EU/1/12/791/001	Solution for injection	C10AX10	29.10.2012

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

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
25.10.2012	Elelyso	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	—	29.10.2012

— **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
1.10.2012	Cialis	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/02/237/001-009	3.10.2012
1.10.2012	Conbriza	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/511/001-005	3.10.2012
1.10.2012	Olanzapine Neopharma	Neopharma Limited 57 High Street, Odiham, Hampshire RG29 1LF, United Kingdom	EU/1/07/426/001-011	3.10.2012
1.10.2012	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-005	3.10.2012
4.10.2012	Cimzia	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/09/544/001-002	8.10.2012
4.10.2012	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389/001-009	8.10.2012
4.10.2012	Soliris	Alexion Europe S.A.S. 25, boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	8.10.2012
4.10.2012	Topotecan Eagle	Eagle Laboratories Limited The Clock House, Station Approach, Marlow, Bucks SL7 1NT, UNITED KINGDOM	EU/1/11/744/002	8.10.2012
4.10.2012	Vepacel	Baxter Innovations GmbH Industriestrasse 67, A – 1221 Vienna, Österreich	EU/1/12/752/001-002	8.10.2012
8.10.2012	Biograstim	CT Arzneimittel GmbH Graf-Arco-Strasse 3, 89079 Ulm, Deutschland	EU/1/08/450/001-010	11.10.2012

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
8.10.2012	Comtan	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/081/001-004	10.10.2012
8.10.2012	DuoTrav	Alcon Laboratories (UK) Ltd. Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/06/338/001-003	10.10.2012
8.10.2012	Vidaza	Celgene Europe Ltd 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom	EU/1/08/488/001	10.10.2012
8.10.2012	Zavesca	Actelion Registration Ltd. Cheswick Tower, 13th floor, 389 Cheswick High Road, London W4 4AL, United Kingdom	EU/1/02/238/001	10.10.2012
10.10.2012	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC 54, rue La Boétie, 75008 Paris, France	EU/1/97/046/001-039	12.10.2012
10.10.2012	Biopoin	CT Arzneimittel GmbH Graf-Arco-Strasse 3, 89079 Ulm, Deutschland	EU/1/09/565/001-028	12.10.2012
10.10.2012	Dynastat	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/209/001-008	12.10.2012
10.10.2012	Emend	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262/001-010	15.10.2012
10.10.2012	Karvea	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/97/049/034-039	12.10.2012
10.10.2012	Pylobactell	Torbet Laboratories Limited Unit 14D, Wendover Road, Rackheath Industrial Estate, Norwich, Norfolk NR13 6LH, United Kingdom	EU/1/98/064/001	12.10.2012
10.10.2012	Rapamune	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/01/171/007-010	12.10.2012
10.10.2012	Synagis	AbbVie Ltd. Maidenhead, SL6 4XE, United Kingdom	EU/1/99/117/001-002	12.10.2012
15.10.2012	Ceplene	Meda AB Box 906, SE 170 09 Solna, Sverige	EU/1/08/477/001	17.10.2012

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
15.10.2012	Clopidogrel Apotex	Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland	EU/1/09/568/001-018	17.10.2012
15.10.2012	Olazax	Glenmark Pharmaceuticals s.r.o. City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika	EU/1/09/597/001-005	16.10.2012
23.10.2012	Alimta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/290/001-002	26.10.2012
23.10.2012	Glivec	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/198/001-013	26.10.2012
23.10.2012	Helixate NexGen	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/00/144/001-005	26.10.2012
23.10.2012	Humira	AbbVie Ltd. Maidenhead, SL6 4XE, United Kingdom	EU/1/03/256/001-010	26.10.2012
23.10.2012	Kogenate Bayer	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/00/143/004-013	26.10.2012
23.10.2012	Nplate	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/08/497/001-008	26.10.2012
23.10.2012	NULOJIX	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/694/001-002	26.10.2012
23.10.2012	Osseor	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/287/001-006	26.10.2012
23.10.2012	Prolia	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	26.10.2012
23.10.2012	Protelos	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/04/288/001-006	26.10.2012
23.10.2012	Telzir	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/04/282/001-002	26.10.2012
23.10.2012	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529/001-005	26.10.2012

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
23.10.2012	Visudyne	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/00/140/001	26.10.2012
24.10.2012	Adenuric	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	EU/1/08/447/001-012	26.10.2012
24.10.2012	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	26.10.2012
24.10.2012	Baraclude	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/343/001-007	26.10.2012
24.10.2012	Benlysta	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/700/001-002	26.10.2012
24.10.2012	Brilique	AstraZeneca AB Södertälje S 151 85, Sverige	EU/1/10/655/001-006	26.10.2012
24.10.2012	ChondroCelect	TiGenix NV Romeinse straat 12/2, B-3001 LEUVEN, België	EU/1/09/563/001	26.10.2012
24.10.2012	Cialis	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/02/237/007-008	26.10.2012
24.10.2012	Clopidogrel HCS	HCS bvba H. Kennisstraat 53, B 2650 Edegem, België	EU/1/10/651/001-015	26.10.2012
24.10.2012	Daliresp	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/11/668/001-003	26.10.2012
24.10.2012	Daxas	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/10/636/001-007	26.10.2012
24.10.2012	Dynastat	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/209/005-008	26.10.2012
24.10.2012	EDURANT	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/736/001	26.10.2012
24.10.2012	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/99/126/001-022	26.10.2012

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
24.10.2012	Eviplera	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/11/737/001-002	26.10.2012
24.10.2012	Exjade	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/356/001-009	26.10.2012
24.10.2012	Ganfort	Allergan Pharmaceuticals Ireland Castlebar Road, Westport, Co. Mayo, Ireland	EU/1/06/340/001-002	26.10.2012
24.10.2012	Humira	AbbVie Ltd. Maidenhead, SL6 4XE, United Kingdom	EU/1/03/256/001-010	26.10.2012
24.10.2012	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026/001-002	26.10.2012
24.10.2012	Kinzalkomb	Bayer Pharma AG Berlin 13342, Deutschland	EU/1/02/214/001-015	26.10.2012
24.10.2012	Komboglyze	Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/11/731/001-014	26.10.2012
24.10.2012	Libertek	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/11/666/001-003	26.10.2012
24.10.2012	MicardisPlus	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/02/213/001-023	26.10.2012
24.10.2012	Multaq	Sanofi 54, rue La Boétie, 75008 Paris, France	EU/1/09/591/001-004	26.10.2012
24.10.2012	Norvir	AbbVie Ltd. Maidenhead, SL6 4XE, United Kingdom	EU/1/96/016/001 EU/1/96/016/003-008	26.10.2012
24.10.2012	NovoSeven	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/96/006/001-011	26.10.2012
24.10.2012	Onduarp	Boehringer Ingelheim International GmbH Binger Str. 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729/001-006	26.10.2012
24.10.2012	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/08/452/001	26.10.2012

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
24.10.2012	Possia	AstraZeneca AB Södertälje S 151 85, Sverige	EU/1/10/656/001-006	26.10.2012
24.10.2012	PREZISTA	Janssen-Cilag International NV Turnhoutseweg 30, B - 2340 Beerse, België	EU/1/06/380/001-006	26.10.2012
24.10.2012	PritorPlus	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/02/215/001-021	26.10.2012
24.10.2012	ReFacto AF	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/99/103/001-009	26.10.2012
24.10.2012	RotaTeq	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, Lyon 69007, France	EU/1/06/348/001-002	26.10.2012
24.10.2012	SonoVue	Bracco International B.V. Strawinskylaan 3051, 1077 ZX Amsterdam, Nederland	EU/1/01/177/002	26.10.2012
24.10.2012	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498/001-008	26.10.2012
24.10.2012	Trajenta	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/11/707/001-011	26.10.2012
24.10.2012	Valdoxan	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/08/499/001-008	26.10.2012
24.10.2012	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/08/470/001-013 EU/1/08/470/016-019	29.10.2012
24.10.2012	Votrient	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	26.10.2012
24.10.2012	Zometa	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/176/001-009	26.10.2012
25.10.2012	Bridion	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/08/466/001-002	29.10.2012
25.10.2012	Capecitabine Krka	KRKA, d.d Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763/001-018	30.10.2012

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
25.10.2012	Cinryze	ViroPharma SPRL-BVBA rue Montoyer 47, 1000 Bruxelles, Belgique/Montoyerstraat 47, 1000 Brussel, België	EU/1/11/688/001	29.10.2012
25.10.2012	Clopidogrel Teva Pharma	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/561/001-011	29.10.2012
25.10.2012	Copalia	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/372/001-039	29.10.2012
25.10.2012	Corlentor	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes, Cedex, France	EU/1/05/317/001-014	29.10.2012
25.10.2012	Dafiro	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/371/001-039	29.10.2012
25.10.2012	Efavirenz Teva	Teva Pharma BV Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/742/001-010	30.10.2012
25.10.2012	Eucreas	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/425/001-018	29.10.2012
25.10.2012	Exforge HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/569/001-060	29.10.2012
25.10.2012	Fasturtec	Sanofi-aventis groupe 54, rue La Boétie, 75008 Paris, France	EU/1/00/170/001-002	26.10.2012
25.10.2012	Ferriprox	Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland	EU/1/99/108/001-006	29.10.2012
25.10.2012	Firazyr	Shire Orphan Therapies GmbH Friedrichstrasse 149, D-10117 Berlin, Deutschland	EU/1/08/461/001-002	29.10.2012
25.10.2012	Glidipion	Actavis Group PTC ehf. Reykjavíkurvegi 76 - 78, 220 Hafnarfjörður, Iceland	EU/1/12/756/001-027	29.10.2012
25.10.2012	Helicobacter test INFAI	INFAI, Institut für biomedizinische Analytik & NMR Imaging GmbH Universitätsstrasse 142, D - 44799 Bochum, Deutschland	EU/1/97/045/001-005	29.10.2012
25.10.2012	Humalog	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/96/007/002 EU/1/96/007/004-006 EU/1/96/007/008 EU/1/96/007/010 EU/1/96/007/015-021 EU/1/96/007/023-038	30.10.2012

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
25.10.2012	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720/001-002	29.10.2012
25.10.2012	Instanyl	Nycomed Danmark ApS Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/09/531/001-021	29.10.2012
25.10.2012	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/576/001-042	30.10.2012
25.10.2012	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436/001-002	30.10.2012
25.10.2012	Jentadueto	Boehringer Ingelheim International GmbH Binger Str. 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/12/780/029-034	30.10.2012
25.10.2012	Kaletra	AbbVie Ltd. Maidenhead, SL6 4XE, United Kingdom	EU/1/01/172/001-008	30.10.2012
25.10.2012	Kepivance	Swedish Orphan Biovitrum AB (publ) SE-112 76, Stockholm, Sverige	EU/1/05/314/001	29.10.2012
25.10.2012	Kineret	Swedish Orphan Biovitrum AB (publ) SE-112 76, Stockholm, Sverige	EU/1/02/203/001-004	30.10.2012
25.10.2012	Liprolog	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/01/195/001-027	29.10.2012
25.10.2012	Olanzapine Glenmark	Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom	EU/1/09/587/001-017	29.10.2012
25.10.2012	Olanzapine Glenmark Europe	Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom	EU/1/09/588/001-012	29.10.2012
25.10.2012	Olanzapine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/08/475/001-060	29.10.2012
25.10.2012	Olazax Disperzi	Glenmark Pharmaceuticals s.r.o. City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika	EU/1/09/592/001-005	29.10.2012
25.10.2012	Procoralan	Les Laboratoires Servier 50, rue Carnot, 92284 Suresnes cedex, France	EU/1/05/316/001-014	29.10.2012

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
25.10.2012	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	EU/1/08/462/001-012	30.10.2012
25.10.2012	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508/001-011	29.10.2012
25.10.2012	Temomedac	medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstrasse 3, D-20354 Hamburg - Deutschland	EU/1/09/605/001-012	29.10.2012
25.10.2012	Temozolomide HEXAL	HEXAL AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/10/616/001-002 EU/1/10/616/005-006 EU/1/10/616/009-010 EU/1/10/616/013-014 EU/1/10/616/017-018 EU/1/10/616/021-022 EU/1/10/616/025-036	30.10.2012
25.10.2012	Temozolomide Sandoz	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/10/617/001-002 EU/1/10/617/005-006 EU/1/10/617/009-010 EU/1/10/617/013-014 EU/1/10/617/017-018 EU/1/10/617/021-022 EU/1/10/617/025-036	30.10.2012
25.10.2012	Temozolomide SUN	Sun Pharmaceuticals Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/697/001-024	30.10.2012
25.10.2012	Temozolomide Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/09/606/001-012	29.10.2012
25.10.2012	Topotecan Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/09/552/001-004	29.10.2012
25.10.2012	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386/019-020	29.10.2012
25.10.2012	Tracleer	Actelion Registration Ltd Chiswick Tower 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220/001-006	30.10.2012
25.10.2012	Tredaptive	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/459/001-014	29.10.2012
25.10.2012	Trevaclyn	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/458/001-014	29.10.2012

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
25.10.2012	Twynsta	Boehringer Ingelheim International GmbH Binger Strasse 173 - D - 55216 Ingelheim am Rhein, Deutschland	EU/1/10/648/001-028	29.10.2012
25.10.2012	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423/001-003	29.10.2012
29.10.2012	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19, NL-2353 EW Leiderdorp, Nederland	EU/1/07/387/009-010 EU/1/07/387/016 EU/1/07/387/026	1.11.2012
29.10.2012	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185/001-022 EU/1/01/185/031-111	1.11.2012
29.10.2012	ATryn	GTC Biotherapeutics UK Limited 10 Norwich Street, London EC4A 1BD, United Kingdom	EU/1/06/355/001-003	6.11.2012
29.10.2012	Biograstim	CT Arzneimittel GmbH Graf-Arco-Strasse 3, 89079 Ulm, Deutschland	EU/1/08/450/001-010	5.11.2012
29.10.2012	Bronchitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire, SL1 7LW, United Kingdom	EU/1/12/760/001-002	1.11.2012
29.10.2012	Byetta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/06/362/001-004	1.11.2012
29.10.2012	Caelyx	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/96/011/001-004	5.11.2012
29.10.2012	CANCIDAS	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/01/196/001 EU/1/01/196/003	6.11.2012
29.10.2012	Dificlir	Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland	EU/1/11/733/001-004	31.10.2012
29.10.2012	Docetaxel Mylan	Mylan S.A.S 117 allée des Parcs, 69 800 Saint Priest, France	EU/1/11/748/001-006	6.11.2012
29.10.2012	Esbriet	InterMune UK Ltd Euston Tower, Floor 32, 286 Euston Road, London, NW1 3DP, United Kingdom	EU/1/11/667/001-004	1.11.2012
29.10.2012	Exforge	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/370/001-039	31.10.2012

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29.10.2012	Firdapse	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/09/601/001	1.11.2012
29.10.2012	Foscan	Biolitec pharma Ltd United Drug House, Magna Drive, Dublin 24, Ireland	EU/1/01/197/001-002	31.10.2012
29.10.2012	Fycompa	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertsforshire AL10 9SN, United Kingdom	EU/1/12/776/001-023	31.10.2012
29.10.2012	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/642/001-004	31.10.2012
29.10.2012	Icandra	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/484/001-018	1.11.2012
29.10.2012	Imprida	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/373/001-039	31.10.2012
29.10.2012	INOmax	INO Therapeutics AB SE-181 81 Lidingö, Sverige	EU/1/01/194/001-004	1.11.2012
29.10.2012	Irbesartan/ Hydrochlorothiazide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/583/001-075	1.11.2012
29.10.2012	Javlor	Pierre Fabre Médicament 45, place Abel Gance, F-92100 Boulogne, France	EU/1/09/550/001-012	31.10.2012
29.10.2012	Leflunomide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/675/001-010	6.11.2012
29.10.2012	Levetiracetam Actavis Group	Actavis Group PTC ehf. ReykjavÍkurvegur 76-78, Hafnarfjörður 220, Iceland	EU/1/11/738/001-003	1.11.2012
29.10.2012	Lucentis	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/374/001	1.11.2012
29.10.2012	Myclausen	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, 14167 Berlin, Deutschland	EU/1/10/647/001-004	31.10.2012
29.10.2012	Myocet	Cephalon Europe 5 Rue Charles Martigny, Maisons Alfort 94700, France	EU/1/00/141/001-002	5.11.2012

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
29.10.2012	Nimvastid	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/525/001-050	5.11.2012
29.10.2012	Pelzont	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/460/001-014	31.10.2012
29.10.2012	Pixuvri	CTI Life Sciences Ltd Biopark, Broadwater Road, Welwyn Garden City, Hertfordshire AL73AX, United Kingdom	EU/1/12/764/001	6.11.2012
29.10.2012	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 54, rue La Boétie, 75008 Paris, France	EU/1/98/069/001a-001b EU/1/98/069/002a-002b EU/1/98/069/003a-003b EU/1/98/069/004a-004b EU/1/98/069/005a-005b EU/1/98/069/006a-006b EU/1/98/069/007a-007b EU/1/98/069/008-010 EU/1/98/069/011a-011b EU/1/98/069/012	2.11.2012
29.10.2012	Plenadren	ViroPharma SPRL Rue Montoyer 47, 1000 Bruxelles/Brussel, Belgique/België	EU/1/11/715/001-002	6.11.2012
29.10.2012	Pravafenix	LABORATOIRES SMB SA 26-28 rue de la Pastorale, 1080 Bruxelles, Belgique/26-28 Herdersliedstraat, 1080 Brussel, België	EU/1/11/679/007	6.11.2012
29.10.2012	Pumarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/10/664/001	6.11.2012
29.10.2012	Raloxifene Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/627/001-003	6.11.2012
29.10.2012	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	EU/1/08/462/001-012	2.11.2012
29.10.2012	Rapiscan	Rapidscan Pharma Solutions EU Ltd. Regent's Place, 338 Euston Road, London NW1 3BT, UK	EU/1/10/643/001	6.11.2012
29.10.2012	Repaglinide Krka	KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/579/001-018	5.11.2012
29.10.2012	Repaglinide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/530/001-015	6.11.2012
29.10.2012	Repso	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/674/001-010	1.11.2012

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
29.10.2012	Ribavirin Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/10/634/001-011	1.11.2012
29.10.2012	Rienso	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/12/774/001-004	31.10.2012
29.10.2012	Sabervel	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/12/765/001-009	31.10.2012
29.10.2012	Samsca	Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1LX, United Kingdom	EU/1/09/539/001-004	31.10.2012
29.10.2012	Stelara	Janssen-Cilag International NV Turnhoutseweg 30, B - 2340 Beerse, België	EU/1/08/494/001-002	5.11.2012
29.10.2012	Sycrest	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640/001-006	6.11.2012
29.10.2012	Tasmar	Meda AB Pipers väg 2A, SE-170 73 Solna, Sverige	EU/1/97/044/001-009	1.11.2012
29.10.2012	Telmisartan Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76 78, 220 Hafnarfjörður, Iceland	EU/1/10/639/001-030	31.10.2012
29.10.2012	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/610/001-062	31.10.2012
29.10.2012	Telmisartan Teva Pharma	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/11/719/001-062	31.10.2012
29.10.2012	Teysuno	Nordic Group BV Siriusdreef 22, 2132 WT Hoofddorp, Nederland	EU/1/11/669/001-005	6.11.2012
29.10.2012	Topotecan Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633/001-002	31.10.2012
29.10.2012	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-027	1.11.2012
29.10.2012	Xarelto	Bayer Pharma AG 13342 Berlin, Deutschland	EU/1/08/472/011-021	31.10.2012

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
29.10.2012	Zalasta	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/07/415/001-056	6.11.2012
29.10.2012	Zomarist	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/483/001-018	1.11.2012
31.10.2012	Adjupanrix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/578/001	6.11.2012
31.10.2012	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstr. 100, D-60318 Frankfurt/Main - Deutschland	EU/1/02/218/001-003 EU/1/02/218/005-030	6.11.2012
31.10.2012	Copalia HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/575/001-060	6.11.2012
31.10.2012	Dafiro HCT	Novartis Europharm Ltd Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/574/001-060	6.11.2012
31.10.2012	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/07/384/003-005	6.11.2012
31.10.2012	Ebixa	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/02/219/001-003 EU/1/02/219/005-049	6.11.2012
31.10.2012	Ifirmasta	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/480/001-024	6.11.2012
31.10.2012	Kaletra	AbbVie Ltd. Maidenhead, SL6 4XE, United Kingdom	EU/1/01/172/001-008	6.11.2012
31.10.2012	Kiovig	Baxter AG Industriestraße 67, A - 1221 Wien, Österreich	EU/1/05/329/001-006	6.11.2012
31.10.2012	Levetiracetam Accord	Accord Healthcare Limited 5th Floor Charles House, 108/110 Finchley road, London NW3 5JJ, United Kingdom	EU/1/11/712/001-040	6.11.2012
31.10.2012	Levetiracetam Actavis	Actavis Group PTC ehf. Reykjavikurvegur 76-78, 220 Hafnarfjordur, Iceland	EU/1/11/713/001-040	6.11.2012

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
31.10.2012	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444/001-012	7.11.2012
31.10.2012	Repaglinide Accord	Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF United Kingdom	EU/1/11/743/001-015	6.11.2012
31.10.2012	Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/09/599/001-018	6.11.2012
31.10.2012	Siklos	ADDMEDICA 101, rue Saint Lazare, Paris 75009, France	EU/1/07/397/001-004	6.11.2012
31.10.2012	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/08/445/001-014	6.11.2012
31.10.2012	Tolura	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/10/632/001-021	6.11.2012
31.10.2012	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/11/710/001-007	6.11.2012

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

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
4.10.2012	Daliresp	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	—	8.10.2012
4.10.2012	Daxas	Nycomed GmbH Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	—	8.10.2012

— **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
24.10.2012	Rilonacept Regeneron	Regeneron UK Limited 40 Bank Street, E14 5DS London, United Kingdom	EU/1/09/582/001	26.10.2012

— **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
10.10.2012	Acticam	Ecuphar NV Legeweg 157-I, B-8020 Oostkamp, België	EU/2/08/088/004	12.10.2012
15.10.2012	Oxyglobin	OPK Biotech Netherlands BV Teleportboulevard 140, 1043EJ Amsterdam, Nederland	EU/2/99/015/001-004	16.10.2012
23.10.2012	ProteqFlu	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/03/037/005	26.10.2012
24.10.2012	Pirsue	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/00/027/001-003	26.10.2012
25.10.2012	Dexdomitor	Orion Corporation Orionintie 1, FIN-02200 Espoo, Suomi	EU/2/02/033/001-004	30.10.2012
25.10.2012	Posatex	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/08/081/001-003	29.10.2012
25.10.2012	Stronghold	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/99/014/001-012	29.10.2012
29.10.2012	Improvac	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/2/09/095/001-006	1.11.2012
29.10.2012	Loxicom	Norbrook Laboratories Limited Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090/001-028	31.10.2012
29.10.2012	Meloxidyl	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/06/070/009	31.10.2012
29.10.2012	Previcox	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/04/045/001-007	6.11.2012
29.10.2012	Procox	Bayer Animal Health GmbH 51368 Leverkusen, Deutschland	EU/2/11/123/001-002	2.11.2012
29.10.2012	RevitaCAM	Abbott Laboratories Limited Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4XE, UNITED KINGDOM	EU/2/12/138/001-003	31.10.2012
29.10.2012	Suvaxyn PCV	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/09/099/001-006	1.11.2012
31.10.2012	PRILACTONE	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/07/074/001-009	6.11.2012

— **Lift of suspension of a marketing authorization (Article 45 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
10.10.2012	Suvaxyn PCV	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/09/099/001-006	12.10.2012

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

The European Medicines Agency
7, Westferry Circus,
Canary Wharf
UK - LONDON E14 4H

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 October 2012 to 31 October 2012

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2012/C 371/04)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
10.10.2012	Aminocaproic acid containing medicinal products (antifibrynolitics)	See Annex I	See Annex I	12.10.2012
8.10.2012	Mometasone Furoate Sandoz and associated names	See Annex II	See Annex II	9.10.2012
10.10.2012	Tranexamic acid containing medicinal products (antifibrynolitics)	See Annex III	See Annex III	12.10.2012
8.10.2012	Baytril	See Annex IV	See Annex IV	9.10.2012

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX I

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Aminocaproic acid containing medicinal products with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
ES - Spain	ROTTAPHARM, S.L. Avda. Diagonal 67-69 08019 Barcelona España	CAPROAMIN FIDES 4 g SOLUCIÓN INYECTABLE	4 g/10 ml	solution for injection	intravenous use
HU - Hungary	PannonPharma Kft. Pannonpharma út 1. 7720 Pécsvárad Hungary	Acepramin	4 g/10 ml	solution for infusion	intravenous use
PT - Portugal	Bial - Aristegui, Produtos Farmacêuticos, S.A. À Av. da Siderurgia Nacional Apartado 100 4745-457 S. Mamede do Coronado Portugal	Epsicaprom 25	2 500 mg/10 ml	Solution for infusion	intravenous use

ANNEX II

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTH OF THE MEDICINAL PRODUCT, ROUTE OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES

Member State EU/EEA	Applicant	Name	Strength	Pharmaceutical form	Route of administration
Belgium	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Sandoz 50 mcg/dosis neusspray, suspensie	50 microgram/dose	nasal spray, suspension	nasal use
Czech Republic	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mommox 0,05 mg/dávku	50 microgram/dose	nasal spray, suspension	nasal use
Denmark	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Sandoz	50 microgram/dose	nasal spray, suspension	nasal use
Estonia	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Nasometin	50 microgram/dose	nasal spray, suspension	nasal use
Finland	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone furoate Sandoz	50 microgram/dose	nasal spray, suspension	nasal use

Member State EU/EEA	Applicant	Name	Strength	Pharmaceutical form	Route of administration
France	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	MOMETASONE Sandoz 50 microgrammes/dose, suspension pour pulvérisation nasale	50 microgram/dose	nasal spray, suspension	nasal use
Germany	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasonfuroat Sandoz 50 Mikrogramm/Sprühstoß Nasenspray, Suspension	50 microgram/dose	nasal spray, suspension	nasal use
Greece	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Furoate/Sandoz	50 microgram/dose	nasal spray, suspension	nasal use
Hungary	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometason Sandoz 50 mikrogramm/adag oldatos orrspray	50 microgram/dose	nasal spray, suspension	nasal use
Italy	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	MOMETASONE FUROATO SANDOZ 50 microgrammi/erogazione, spray nasale	50 microgram/dose	nasal spray, suspension	nasal use
Luxembourg	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometason Sandoz 50 mcg/dose spray nasale	50 microgram/dose	nasal spray, suspension	nasal use

Member State EU/EEA	Applicant	Name	Strength	Pharmaceutical form	Route of administration
Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasonfuroaat Sandoz 50 microgram/dosis, neusspray, suspensie	50 microgram/dose	nasal spray, suspension	nasal use
Norway	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Sandoz	50 microgram/dose	nasal spray, suspension	nasal use
Poland	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Nasometin	50 microgram/dose	nasal spray, suspension	nasal use
Portugal	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasona Sandoz	50 microgram/dose	nasal spray, suspension	nasal use
Romania	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometazonă furoat Sandoz 50 micrograme/doza, spray nazal, suspensie	50 microgram/dose	nasal spray, suspension	nasal use
Slovak Republic	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Sandoz 50 mikrogramov	50 microgram/dose	nasal spray, suspension	nasal use

Member State EU/EEA	Applicant	Name	Strength	Pharmaceutical form	Route of administration
Slovenia	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	FUMOMO 50 mikrogramov/vpih pršilo za nos, suspenzija	50 microgram/dose	nasal spray, suspension	nasal use
Spain	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasona Sandoz 50 mcg/dosis suspensión para nebulización nasal	50 microgram/dose	nasal spray, suspension	nasal use
Sweden	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Sandoz	50 microgram/dose	nasal spray, suspension	nasal use
United Kingdom	Sandoz B.V. Veluwezoom 22 1327 AH Almere P.O. box 10332 1301 AH Almere The Netherlands	Mometasone Furoate 50 micrograms/dose, nasal spray, suspension	50 microgram/dose	nasal spray, suspension	nasal use

ANNEX III

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Tranexamic acid containing medicinal products with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Cyklokapron - Ampullen	0,5 g/5 ml	Solution for injection	intravenous use
BE - Belgium	PFIZER S.A.N.V. Bld de la Plaine 17 1050 Brussels Belgium	Cyklokapron	100 mg/5 ml	Solution for injection	intravenous use
BE - Belgium	Eumedica S.A. Winston Churchilllaan 67 1180 Brussels Belgium	Exacyl 500	500 mg/5 ml	Solution for injection	intravenous use
CY - Cyprus	MEDOCHEMIE LTD, 1-10 CONSTANTINOUPOLEOS STREET, P.O.BOX 51409, 3505 LEMESOS, CYPRUS	AZEPTIL INJECTION 500 MG/5 ML	500 MG/5 ML	INJECTION	intravenous use
CY - Cyprus	MEDOCHEMIE LTD, 1-10 CONSTANTINOUPOLEOS STREET, P.O.BOX 51409, 505 LEMESOS, CYPRUS	AZEPTIL INJECTION 250 MG/5 ML	250 MG/5 ML	INJECTION	intravenous use
CZ - Czech Republic	Sanofi-Aventis, s.r.o., Evropská 846/176a, 160 00 Praha 6, Czech Republic	Exacyl	100 mg/ml	Solution for injection	intravenous use

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin	Cyklokapron-Injektionslösung	500 mg/5 ml	Solution for injection	intravenous use
DK - Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Tranexamsyre 'Pfizer'	100 mg/ml	Solution for injection	intravenous use
EL - Greece	A. NIKOLAKOPOULOS A.E. GALATSIOU AVENUE 115, Athens 11146	TRANSAMIN	500 MG/5 ML	Solution for Injection or infusion	intravenous use
ES - Spain	ROTTAPHARM S.L. Avda. Diagonal 67-69 08019 Barcelona España	AMCHAFIBRIN 500 mg SOLUCIÓN INYECTABLE	500 mg/5 ml	solution for injection	intravenous use
ET - Estonia	Pfizer Enterprises SARL Round-Point du Kirchberg 51, Avenue J.F. Kennedy L-1855 Luxembourg	CYKLOKAPRON	100 mg/ml	solution for injection	intravenous use
FI - Finland	Oy Leiras Finland Ab Paciuksenkatu 21 PL 1406 00101 Helsinki Finland	CAPRILON	100 mg/ml	Solution for injection	intravenous use
FR - France	Sanofi Aventis France 1-13, bd Romain Rolland 75014 Paris France	Exacyl 0,5 g/5 ml I.V., solution injectable	0,5 g/5 ml	solution for injection	intravenous use
HU - Hungary	sanofi-aventis Zrt. Tó u. 1-5. 1045 Budapest, Hungary	Exacyl	0,5 g/5 ml	solution for injection	intravenous use

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Pharmacia Ireland Ltd, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 Ireland	Cyklokapron 500 mg/5 ml solution for injection or infusion	100 mg/ml	Solution for injection	intravenous use
IS - Iceland	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Tranexamsyre 'Pfizer'	100 mg/ml	Solution for injection	intravenous use
IT - Italy	Rottapharm S.p.A. Via Valosa di Sopra, 9 20052 Monza - Italy	UGUROL	500 mg/5 ml	solution for injection	intravenous use
IT - Italy	Istituto Farmacobiologico Malesci S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (Firenze) Italy	TRANEX	500 mg/5 ml	solution for injection	intravenous use
IT - Italy	Bioindutria Laboratorio Italiano Medicinali spa Via De Ambrosiis, 2 15067 Novi Ligure Alessandria Italy	ACIDO TRANEXAMICO BIOINDUTRIA L.I.M.	500 mg/5 ml	solution for injection	intravenous use
LU - Luxembourg	Eumedica SA 67, Avenue Winston Churchill B-1180 Bruxelles	EXACYL	500 mg/5 ml	solution for injection	intravenous use
LU - Luxembourg	PFIZER S.A.N.V. Bld de la Plaine 17 1050 Brussels Belgium	Cyklokapron	100 mg/ml	Solution for injection	Intravenous use
NL - Netherlands	Pfizer B.V. Rivium Westlaan 142 2909 LD, Capelle a/d Ijssel	Cyklokapron, oplossing voor injectie 100 mg/ml	100 mg/ml	solution for injection	intravenous use

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
NO - Norway	Pfizer AS Postboks 3 1324 Lysaker Norway	CYKLOKAPRON	100 mg/ml	injection for solution	intravenous use
PL - Poland	Warszawskie Zakłady Farmaceutyczne POLFA S.A. 22/24 karolkowa st. 01-207 Warsaw, Poland	Exacyl	100 mg/ml	solution for infusion	intravenous use
PL - Poland	Sanofi-Aventis France Boulevard Romain Rolland 1-13, F-75014 Paris, France	Exacyl	100 mg/ml	solution for infusion	intravenous use
SE - Sweden	Pfizer AB 191 90 Sollentuna Sweden	Cyklokapron	100 mg/ml	Solution for injection	intravenous use
UK - United Kingdom	Pharmacia Limited Walton Oaks, Dorking Road, Tadworth Surrey KT20 7NS United Kingdom	CYKLOKAPRON INJECTION 500 MG/ML	500 mg/ml	Solution for Injection	intravenous use

ANNEX IV

Condition of the marketing authorisations

The National Competent Authorities shall ensure that the following condition is fulfilled by the marketing authorisation holders:

— The marketing authorisation holders should substantiate the dosing regimen in rabbits taking into account the current MIC distribution for the target pathogens, the variability in pharmacokinetics resulting from administration of enrofloxacin via the drinking water to groups of rabbits under field conditions and with the goal to ensure sustainable effective treatment.

— Residue depletion studies should be provided for any proposed new dosage regimen. A shorter or lower dose regimen than the current 10 mg/kg for 5 days needs to be substantiated by new clinical data.

The results of those studies should be provided to the relevant Authorities for assessment not later than 18 months after the Commission Decision on this referral procedure.

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