

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 2013 to 30 November 2013

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

(2013/C 380/01)

— 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
11.11.2013	Levodopa-Carbidopa-Entacapone Sandoz	levodopa / carbidopa / entacapone	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/13/859	Film-coated tablet	N04BA03	13.11.2013
13.11.2013	NovoEight	turoctocog alfa	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/13/888	Powder and solvent for solution for injection	B02BD02	15.11.2013
13.11.2013	Relvar Ellipta	fluticasone furoate/vilanterol trifrenatate	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/13/886	Inhalation powder, pre-dispensed	R03AK10	14.11.2013

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

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
13.11.2013	Vitekta	elvitegravir	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/883	Film-coated tablet	J05AX11	14.11.2013
13.11.2013	Xofigo	Radium Ra 223 dichloride	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/13/873	Solution for injection	V10XX03	14.11.2013
15.11.2013	ABILIFY MAINTENA	Aripiprazole	Otsuka Pharmaceutical Europe Ltd. Gallions Wexham Springs, Framewood Road, Wexham, Slough, Berkshire SL3 6PJ, United Kingdom	EU/1/13/882	Powder and solvent for prolonged-release suspension for injection	N05AX12	19.11.2013
15.11.2013	Invokana	canagliflozin	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/13/884	Film-coated tablet	A10BX11	19.11.2013
15.11.2013	Kadcyla	Trastuzumab emtansine	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/885	Powder for concentrate for solution for infusion	L01XC14	19.11.2013
15.11.2013	Lidocaine/Prilocaine Plethora	lidocaine / prilocaine	Plethora Solutions Limited Hampden House, Monument Business Park, Chalgrove, OX44 7RW United Kingdom	EU/1/13/881	Cutaneous spray, solution	N01BB20	19.11.2013
20.11.2013	Intelence	etravirine	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/08/468	Tablet	J05AG04	22.11.2013

— **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
8.11.2013	Xeljanz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/13/874	12.11.2013

— **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
11.11.2013	Edarbi	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/11/734	12.11.2013
11.11.2013	Ipreziv	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/11/735	12.11.2013
11.11.2013	Oprymeia	Krka, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/469	13.11.2013
11.11.2013	Rapamune	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/01/171	13.11.2013
13.11.2013	Actos	Takeda Pharma A/S Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/00/150	15.11.2013
13.11.2013	Competact	Takeda Pharma A/S PO Box 88, Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/06/354	14.11.2013
13.11.2013	Efient	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/08/503	15.11.2013
13.11.2013	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/126	15.11.2013
13.11.2013	Filgrastim Hexal	Hexal AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/08/496	15.11.2013

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13.11.2013	Firmagon	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 København S, Danmark	EU/1/08/504	15.11.2013
13.11.2013	Firmagon	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 København S, Danmark	EU/1/08/504	15.11.2013
13.11.2013	Fycompa	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/12/776	15.11.2013
13.11.2013	Glubrava	Takeda Pharma A/S Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/07/421	15.11.2013
13.11.2013	Glustin	Takeda Pharma A/S Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/00/151	15.11.2013
13.11.2013	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026	15.11.2013
13.11.2013	Jakavi	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/12/773	15.11.2013
13.11.2013	Kuvan	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/08/481	15.11.2013
13.11.2013	Ranexa	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/08/462	22.11.2013
13.11.2013	Rasilez HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491	15.11.2013
13.11.2013	ReFacto AF	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/103	15.11.2013

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13.11.2013	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	15.11.2013
13.11.2013	Silodyx	Recordati Ireland Ltd. Raheens East, Ringaskiddy Co. Cork, Ireland	EU/1/09/607	15.11.2013
13.11.2013	Tandemact	Takeda Pharma A/S Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/06/366	15.11.2013
13.11.2013	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498	15.11.2013
13.11.2013	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498	15.11.2013
13.11.2013	Urorec	Recordati Ireland Ltd. Raheens East, Ringaskiddy Co. Cork, Ireland	EU/1/09/608	15.11.2013
13.11.2013	Valdoxan	Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France	EU/1/08/499	15.11.2013
13.11.2013	Valdoxan	Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France	EU/1/08/499	15.11.2013
13.11.2013	Vidaza	Celgene Europe Limited Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom	EU/1/08/488	15.11.2013
13.11.2013	Zarzio	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/08/495	15.11.2013
15.11.2013	Alimta	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/290	19.11.2013
15.11.2013	Azilect	Teva Pharma GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/04/304	19.11.2013

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15.11.2013	Bretaris Genuair	Almirall, S.A. Ronda General Mitre, 151, E-08022 Barcelona, España	EU/1/12/781	18.11.2013
15.11.2013	Ecansya	Krka, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	19.11.2013
15.11.2013	Eklira Genuair	Almirall, S.A. Ronda General Mitre, 151, E-08022 Barcelona, España	EU/1/12/778	18.11.2013
15.11.2013	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Bristol-Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/11/691	18.11.2013
15.11.2013	Kineret	Swedish Orphan Biovitrum AB (publ) SE-112 76, Stockholm, Sverige	EU/1/02/203	19.11.2013
15.11.2013	Multaq	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/09/591	19.11.2013
15.11.2013	Neulasta	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/02/227	19.11.2013
15.11.2013	PREZISTA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/06/380	19.11.2013
15.11.2013	Rapiscan	Rapidscan Pharma Solutions EU Ltd. Regent's Place, 338 Euston Road, London NW1 3BT, United Kingdom	EU/1/10/643	19.11.2013
15.11.2013	Sutent	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/06/347	19.11.2013
15.11.2013	Tygacil	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/06/336	19.11.2013
15.11.2013	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	19.11.2013

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20.11.2013	Angiox	The Medicines Company UK Ltd 115 L Milton Park, Abingdon, Oxfordshire OX14 4SA, United Kingdom	EU/1/04/289	22.11.2013
20.11.2013	Beromun	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/99/097	22.11.2013
20.11.2013	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, B-1831 Diegem, België	EU/1/08/473	22.11.2013
20.11.2013	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/00/170	22.11.2013
20.11.2013	HALAVEN	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/11/678	25.11.2013
20.11.2013	Hycamtin	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/96/027	22.11.2013
20.11.2013	Kalydeco	Vertex Pharmaceuticals (U.K.) Limited Cardinal Point, Park Road, Rickmansworth, Herts WD3 1RE, United Kingdom	EU/1/12/782	22.11.2013
20.11.2013	Mabthera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/067	25.11.2013
20.11.2013	Opgenra	Olympus Biotech International Limited Raheen Business Park, Limerick, Ireland	EU/1/08/489	25.11.2013
20.11.2013	Plenadren	ViroPharma SPRL-BVBA rue Montoyer 47, 1000 Bruxelles, Belgique / Montoyerstraat 47, 1000 Brussel, België	EU/1/11/715	21.11.2013
20.11.2013	Prevenar 13	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/590	22.11.2013

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20.11.2013	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/05/330	22.11.2013
20.11.2013	Telzir	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/282	22.11.2013
20.11.2013	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/424	22.11.2013
20.11.2013	Zoledronic acid Teva Pharma	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/772	22.11.2013
25.11.2013	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	27.11.2013
25.11.2013	Elaprase	Shire Human Genetic Therapies AB Svärdvägen 11D, SE-182 33 Danderyd, Sverige	EU/1/06/365	27.11.2013
25.11.2013	GILENYA	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/677	27.11.2013
25.11.2013	Pandemic influenza vaccine H5N1 BAXTER	Baxter AG Industriestraße 67, A-1221 Wien, Österreich	EU/1/09/571	27.11.2013
25.11.2013	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267	27.11.2013
25.11.2013	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508	27.11.2013
25.11.2013	Vepacel	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/12/752	27.11.2013
28.11.2013	Jalra	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485	29.11.2013

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28.11.2013	Xiliarx	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/486	29.11.2013
29.11.2013	Arixtra	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/02/206	2.12.2013
29.11.2013	Busilvex	Pierre Fabre Médicament 45 place Abel Gance, F-92654 Boulogne-Billancourt CEDEX, France	EU/1/03/254	3.12.2013
29.11.2013	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	4.12.2013
29.11.2013	Preotact	NPS Pharma Holdings Limited Grand Canal House, 1 Grand Canal Street Upper, Dublin 4, Ireland	EU/1/06/339	3.12.2013
29.11.2013	Prevenar	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/00/167	3.12.2013
29.11.2013	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	3.12.2013

— **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
8.11.2013	Onsior	Novartis Animal Health UK Ltd Frimley Business Park, Frimley/Camberley, Surrey, GU16 7SR, United Kingdom	EU/2/08/089	13.11.2013
8.11.2013	Zulvac 1+8 Bovis	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgique	EU/2/12/139	13.11.2013
11.11.2013	Easotic	VIRBAC S.A. 1 ^{ère} Avenue - 2065 m - L.I.D., F-06516 Carros CEDEX, France	EU/2/08/085	13.11.2013

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
13.11.2013	Comfortis	Eli Lilly and Company Ltd Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/10/115	15.11.2013
20.11.2013	CERTIFECT	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/11/125	22.11.2013

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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