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 December 2014 to 31 December 2014

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

(2015/C 032/01)

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

— **Issuing of a marketing authorisation** (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 authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
5.12.2014	Paliperidone Janssen	Paliperidone	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/971	Prolonged release suspension for injection	N05AX13	9.12.2014
8.12.2014	Duloxetine Lilly	Duloxetine	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/972	Gastro-resistant capsule, hard	N06AX21	10.12.2014
8.12.2014	Moventig	Naloxegol	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/962	Film-coated tablet	A06AH03	10.12.2014
16.12.2014	DUAVIVE	Oestrogens conjugated/bazedoxifene	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/14/960	Modified-release tablet	G03CX	18.12.2014
16.12.2014	Lynparza	Olaparib	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/959	Capsule, hard	L01	18.12.2014
19.12.2014	Cyramza	Ramucirumab	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/957	Concentrate for solution for infusion	L01XC	23.12.2014
19.12.2014	Rixubis	Nonacog gamma	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/14/970	Powder and solvent for solution for injection	B02BD04	23.12.2014
22.12.2014	Scenesse	Afamelanotide	Clinuvel UK Limited c/o — Reed Smith, Broadgate Tower, Third Floor, 20 Primrose Street, London, EC2A 2RS, United Kingdom	EU/1/14/969	Implant	D02BB02	29.12.2014

— **Modification of a marketing authorisation** (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 authorisation	Number of the entry in the Community Register	Date of notification
1.12.2014	Desloratadine Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/11/732	3.12.2014
1.12.2014	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/10/642	3.12.2014
1.12.2014	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/576	3.12.2014
1.12.2014	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	EU/1/07/398	3.12.2014
4.12.2014	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614	9.12.2014
4.12.2014	Ratiograstim	Ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444	8.12.2014
4.12.2014	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/445	8.12.2014
5.12.2014	Cystagon	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/97/039	9.12.2014
5.12.2014	Erbitux	Merck KGaA 64271 Darmstadt, Deutschland	EU/1/04/281	9.12.2014
5.12.2014	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	9.12.2014
11.12.2014	Bronchitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire SL1 7LW, United Kingdom	EU/1/12/760	15.12.2014
11.12.2014	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	15.12.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
11.12.2014	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	15.12.2014
11.12.2014	Levetiracetam Ratiopharm	Ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/11/702	15.12.2014
11.12.2014	Removab	Neovii Biotech GmbH Am Haag 6-7, 82166 Graefelfing, Deutschland	EU/1/09/512	15.12.2014
15.12.2014	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134	18.12.2014
15.12.2014	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	17.12.2014
15.12.2014	Levetiracetam Actavis Group	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/738	18.12.2014
15.12.2014	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400	18.12.2014
15.12.2014	Naglazyme	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/05/324	17.12.2014
15.12.2014	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	18.12.2014
15.12.2014	Revestive	NPS Pharma Holdings Limited Grand Canal House, 1 Grand Canal Street Upper, Dublin 4, Ireland	EU/1/12/787	17.12.2014
15.12.2014	Somatropin Biopartners	BioPartners GmbH Kaiserpassage 11, D-72764 Reutlingen, Deutschland	EU/1/13/849	17.12.2014
15.12.2014	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/422	18.12.2014
15.12.2014	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	18.12.2014
16.12.2014	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538	18.12.2014

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16.12.2014	Brintellix	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/13/891	18.12.2014
16.12.2014	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	17.12.2014
16.12.2014	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/00/170	18.12.2014
16.12.2014	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/11/687	18.12.2014
16.12.2014	HyQvia	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/13/840	18.12.2014
16.12.2014	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720	18.12.2014
16.12.2014	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	18.12.2014
16.12.2014	Levetiracetam Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/713	18.12.2014
16.12.2014	Methylthioninium chloride Proveblue	Provepharm S.A.S. 22 Rue Marc Donadille, 13013 Marseille, France	EU/1/11/682	18.12.2014
16.12.2014	NULOJIX	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/694	18.12.2014
16.12.2014	Orphacol	Laboratoires CTRS 63 rue de l'Est, F-92100 Boulogne-Billancourt, France	EU/1/13/870	18.12.2014
16.12.2014	Paglitaz	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/721	18.12.2014
16.12.2014	Pioglitazone Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/757	18.12.2014
16.12.2014	Pioglitazone Teva Pharma	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/758	18.12.2014
16.12.2014	Remsima	Celltrion Healthcare Hungary Kft. Árpád Fejedelem útja 26-28, H-1023 Budapest, Magyarország	EU/1/13/853	18.12.2014

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16.12.2014	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	19.12.2014
16.12.2014	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	17.12.2014
16.12.2014	Stivarga	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/13/858	18.12.2014
16.12.2014	Ultibro Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/862	18.12.2014
16.12.2014	Ulunar Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/14/917	19.12.2014
16.12.2014	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	18.12.2014
16.12.2014	Xoterna Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/863	18.12.2014
16.12.2014	Zelboraf	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/12/751	19.12.2014
19.12.2014	CellCept	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/005	23.12.2014
19.12.2014	InductOs	Medtronic BioPharma B.V. Earl Bakkenstraat 10, NL-6422 PJ Heerlen, Nederland	EU/1/02/226	23.12.2014
19.12.2014	Puregon	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/008	23.12.2014
19.12.2014	Rilutek	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony CEDEX, France	EU/1/96/010	23.12.2014
19.12.2014	Stayveer	Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland	EU/1/13/832	5.1.2015
19.12.2014	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/610	24.12.2014
19.12.2014	Travatan	Alcon Laboratories (UK) Ltd Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom	EU/1/01/199	23.12.2014
19.12.2014	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	23.12.2014
19.12.2014	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	24.12.2014
19.12.2014	Zoledronic acid Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/772	24.12.2014

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Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
22.12.2014	Bovela	Modified live BVDV-1, non-cytopathic parent strain KE-9, Modified live BVDV-2, non-cytopathic parent strain NY-93	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/176	Lyophilisate and solvent for suspension for injection	QI02AD02	29.12.2014

— **Modification of a marketing authorisation** (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 authorisation	Number of the entry in the Community Register	Date of notification
4.12.2014	Gripovac 3	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/09/102	8.12.2014
4.12.2014	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/00/026	8.12.2014
4.12.2014	Respiporc Flu3	IDT Biologika GmbH Am Pharmapark, D-06861 Dessau-Rosslau, Deutschland	EU/2/09/103	8.12.2014
11.12.2014	Comfortis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/10/115	15.12.2014
11.12.2014	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/13/155	15.12.2014
16.12.2014	Pexion	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/12/147	18.12.2014

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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