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 2016 to 31 December 2016

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

(2017/C 028/01)

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([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
5.12.2016	Venclyxto	venetoclax	AbbVie Ltd Vanwall Road, Maidenhead, SL6 4UB, United Kingdom	EU/1/16/1138	Film-coated tablet	L01X	7.12.2016
8.12.2016	Emtricitabine/Tenofovir disoproxil Krka	emtricitabine/tenofovir disoproxil	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/16/1151	Film-coated tablet	J05AR03	12.12.2016
8.12.2016	SomaKit TOC	edotreotide	Advanced Accelerator Applications 20 rue Diesel, F-1630 Saint-Genis-Pouilly, France	EU/1/16/1141	Powder for solution for injection	V09IX09	12.12.2016
8.12.2016	Tenofovir disoproxil Mylan	Tenofovir disoproxil	MYLAN S.A.S 117 Allée des Parcs, 69800 Saint-Priest, France	EU/1/16/1129	Film-coated tablet	J05AF07	12.12.2016
12.12.2016	OCALIVA	obeticholic acid	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	EU/1/16/1139	Film-coated tablet	A05AA04	15.12.2016
12.12.2016	Rekovelle	follitropin delta	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 Copenhagen S, Danmark	EU/1/16/1150		G03GA10	14.12.2016
16.12.2016	Emtricitabine/Tenofovir disoproxil Mylan	emtricitabine/tenofovir disoproxil	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/16/1133	Film-coated tablet	J05AR03	20.12.2016

— **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
2.12.2016	Aclasta	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/05/308	6.12.2016
5.12.2016	Pioglitazone Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/11/722	7.12.2016
5.12.2016	Spedra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/13/841	7.12.2016
5.12.2016	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1126	7.12.2016
8.12.2016	Actraphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/229	12.12.2016
8.12.2016	Actrapid	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/230	12.12.2016
8.12.2016	Adenuric	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, L-1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/08/447	12.12.2016
8.12.2016	Bosulif	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/13/818	12.12.2016
8.12.2016	CONTROLOC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/515	12.12.2016
8.12.2016	Cystadane	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/06/379	12.12.2016
8.12.2016	DuoPlavin	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/10/619	12.12.2016
8.12.2016	Eperzan	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	EU/1/13/908	14.12.2016
8.12.2016	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/677	12.12.2016

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
8.12.2016	Holoclar	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/987	12.12.2016
8.12.2016	Icandra	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/484	12.12.2016
8.12.2016	Lamivudine/Zidovudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/663	12.12.2016
8.12.2016	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292	5.12.2016
8.12.2016	Otezla	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/14/981	12.12.2016
8.12.2016	PANTOZOL Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/517	12.12.2016
8.12.2016	SOMAC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/516	12.12.2016
8.12.2016	Voriconazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/835	12.12.2016
8.12.2016	Zebinix	Bial — Portela & C[a], SA À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/09/514	12.12.2016
8.12.2016	Zoledronic acid Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/12/759	12.12.2016
9.12.2016	Ecansya	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	12.12.2016
12.12.2016	Accofil	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/14/946	14.12.2016
12.12.2016	Aldara	Meda AB Pipers väg 2A, SE-170 73 Solna, Sverige	EU/1/98/080	14.12.2016
12.12.2016	Aripiprazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/15/1045	14.12.2016

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
12.12.2016	Colobreathe	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/747	14.12.2016
12.12.2016	Cometriq	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/13/890	14.12.2016
12.12.2016	Competact	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/06/354	14.12.2016
12.12.2016	Crixivan	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/024	14.12.2016
12.12.2016	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	EU/1/12/770	15.12.2016
12.12.2016	Ebymect	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/15/1051	14.12.2016
12.12.2016	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	14.12.2016
12.12.2016	Eucreas	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/425	14.12.2016
12.12.2016	Flebogamma DIF	Instituto Grifols, S.A. Can Guasch 2, Parets del Vallès, E-08150 Barcelona, Espaňa	EU/1/07/404	14.12.2016
12.12.2016	Glubrava	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/07/421	14.12.2016
12.12.2016	Humira	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/03/256	14.12.2016
12.12.2016	Inflectra	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/13/854	14.12.2016
12.12.2016	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	14.12.2016
12.12.2016	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	14.12.2016
12.12.2016	Komboglyze	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/731	14.12.2016
12.12.2016	Kyprolis	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1060	14.12.2016
12.12.2016	Lynparza	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/959	14.12.2016

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
12.12.2016	Mysimba	Orexigen Therapeutics Ireland Limited 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland	EU/1/14/988	14.12.2016
12.12.2016	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/767	14.12.2016
12.12.2016	NovoMix	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/00/142	14.12.2016
12.12.2016	Optaflu	Seqirus GmbH Emil-von-Behring-Strasse 76, 35041 Marburg, Deutschland	EU/1/07/394	14.12.2016
12.12.2016	Orbactiv	The Medicines Company UK Ltd 115L Milton Park, Abingdon, Oxfordshire OX14 4SA, United Kingdom	EU/1/15/989	14.12.2016
12.12.2016	Pregabalin Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/15/1027	14.12.2016
12.12.2016	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	14.12.2016
12.12.2016	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	14.12.2016
12.12.2016	TAGRISSO	AstraZeneca AB Gärtunavägen, SE-151 85 Södertälje, Sverige	EU/1/16/1086	14.12.2016
12.12.2016	Trulicity	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/956	14.12.2016
12.12.2016	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	14.12.2016
12.12.2016	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/08/470	14.12.2016
12.12.2016	Vipdomet	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/13/843	14.12.2016
12.12.2016	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/918	14.12.2016
12.12.2016	Xigduo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/900	14.12.2016

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
12.12.2016	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/13/846	14.12.2016
12.12.2016	Zomarist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/483	14.12.2016
13.12.2016	GONAL-f	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/95/001	16.12.2016
16.12.2016	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430	21.12.2016
16.12.2016	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/11/749	20.12.2016
16.12.2016	Kentera	Nicobrand Limited 189 Castleroe Road, Coleraine, Northern Ireland BT51 3 RP, United Kindom	EU/1/03/270	20.12.2016
16.12.2016	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278	20.12.2016
16.12.2016	Mixtard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/231	20.12.2016
16.12.2016	Pemetrexed Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1034	20.12.2016
16.12.2016	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	20.12.2016
16.12.2016	RotaTeq	Sanofi Pasteur MSD SAS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/348	20.12.2016
16.12.2016	Sebivo	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/388	20.12.2016
19.12.2016	Entyvio	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/14/923	21.12.2016
19.12.2016	Pemetrexed Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/15/1037	21.12.2016
19.12.2016	Tractocile	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, DK-2300 Copenhagen S, Danmark	EU/1/99/124	21.12.2016
19.12.2016	Visudyne	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/00/140	21.12.2016

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
23.12.2016	Duloxetine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/15/1010	5.1.2017
23.12.2016	Fareston	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/96/004	4.1.2017
23.12.2016	Invirase	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026	4.1.2017
23.12.2016	Mepact	Takeda France SAS Immeuble Pacific, 11-13 cours Valmy, 92800 Puteaux, France	EU/1/08/502	4.1.2017
23.12.2016	Orkambi	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/15/1059	4.1.2017
23.12.2016	Raplixa	Mallinckrodt Pharmaceuticals Ireland Limited College Business & Technology Park Cruiserath, Blanchardstown, Dublin 15, Ireland	EU/1/14/985	4.1.2017
23.12.2016	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/13/901	4.1.2017

— **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
16.12.2016	Budesonide/Formoterol Teva	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/948	20.12.2016
16.12.2016	Budesonide/Formoterol Teva Pharma B.V.	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/950	20.12.2016

— **Issuing 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	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
13.12.2016	Cepedex	dexmedetomidine	CP Pharma Handelsgesellschaft mbH Ostlandring 13, D-31303 Burgdorf, Deutschland	EU/2/16/200	Solution for injection	QN05CM18	15.12.2016
13.12.2016	Halagon	halofuginone	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/16/201	Oral solution	QP51AX08	15.12.2016

— **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
13.12.2016	Parvoduk	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/14/162	15.12.2016
13.12.2016	Zulvac 1 + 8 Bovis	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/139	15.12.2016
14.12.2016	Activyl Tick Plus	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/11/137	16.12.2016
14.12.2016	Porcilis PCV M Hyo	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/14/175	16.12.2016
14.12.2016	Versican Plus DHPPi	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/169	16.12.2016
14.12.2016	Versican Plus DHPPi/L4	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/164	16.12.2016
14.12.2016	Versican Plus DHPPi/L4R	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/163	16.12.2016

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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