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 August 2016 to 31 August 2016

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

(2016/C 362/01)

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

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

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
16.8.2016	Cinqaero	reslizumab	Teva Pharmaceuticals Limited Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX, United Kingdom	EU/1/16/1125	Concentrate for solution for infusion	R03DX08	18.8.2016
18.8.2016	Aerivio Spiromax	salmeterol/fluticasone propionate	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/16/1122	Inhalation powder	R03AK06	22.8.2016
18.8.2016	Airexar Spiromax	salmeterol/fluticasone propionate	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/16/1123	Inhalation powder	R03AK06	22.8.2016
18.8.2016	Nordimet	methotrexate	Nordic Group B.V. Siriusdreef 22, NL-2132 WT Hoofddorp, Nederland	EU/1/16/1124	Solution for injection	L01BA01	22.8.2016

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18.8.2016	Zalmoxis	Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)	MolMed S.p.A. Via Olgettina 58, I-20132 Milano, Italia	EU/1/16/1121	Dispersion for infusion	Pending	23.8.2016
22.8.2016	Atazanavir Mylan	atazanavir	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/16/1091	Capsule, hard	J05AE08	24.8.2016
25.8.2016	Kisplyx	lenvatinib	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/16/1128	Capsule, hard	L01XE29	30.8.2016

— **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
1.8.2016	Aripiprazole Mylan Pharma	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/15/1005	3.8.2016
1.8.2016	Ilaris	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/564	3.8.2016
1.8.2016	Pegasys	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/221	3.8.2016
1.8.2016	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	3.8.2016
1.8.2016	Rasagiline ratiopharm	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/14/977	3.8.2016
1.8.2016	XALKORI	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/793	3.8.2016
8.8.2016	Desloratadine ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/11/746	10.8.2016
8.8.2016	Desloratadine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/732	10.8.2016
8.8.2016	Levetiracetam Actavis Group	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Ísland	EU/1/11/738	10.8.2016
8.8.2016	Plenadren	Shire Services BVBA rue Montoyer 47, 1000 Bruxelles, Belgique/ Montoyerstraat 47, 1000 Brussel, België	EU/1/11/715	10.8.2016
8.8.2016	Zavesca	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/238	10.8.2016
9.8.2016	IDflu	Sanofi Pasteur SA 2 avenue Pont Pasteur, F-69007 Lyon, France	EU/1/08/507	11.8.2016
9.8.2016	Intanza	Sanofi Pasteur MSD SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/08/505	11.8.2016

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9.8.2016	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	11.8.2016
9.8.2016	Memantine ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/13/836	11.8.2016
12.8.2016	Ibandronic acid Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/798	17.8.2016
12.8.2016	Imvanex	Bavarian Nordic A/S Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark	EU/1/13/855	17.8.2016
12.8.2016	Myclausen	Passauer Pharma GmbH Eiderstedter Weg 3, 14129 Berlin, Deutschland	EU/1/10/647	17.8.2016
12.8.2016	Scenesse	Clinuvel UK Limited Devonshire House, 60 Goswell Road, London EC1M 7AD, United Kingdom	EU/1/14/969	17.8.2016
16.8.2016	Aflunov	Seqirus S.r.l. Via Fiorentina, 1, Siena, Italia	EU/1/10/658	18.8.2016
16.8.2016	Dasselta	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/739	18.8.2016
16.8.2016	Eylea	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/12/797	18.8.2016
16.8.2016	HALAVEN	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/11/678	18.8.2016
16.8.2016	Mekinist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/14/931	18.8.2016
18.8.2016	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	22.8.2016
18.8.2016	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	22.8.2016
18.8.2016	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/924	22.8.2016
18.8.2016	Sevelamer carbonate Zentiva	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/14/952	22.8.2016

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18.8.2016	Tracleer	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220	22.8.2016
18.8.2016	Truvada	Gilead Sciences International Ltd. Cambridge, CB21 6GT, United Kingdom	EU/1/04/305	22.8.2016
18.8.2016	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	22.8.2016
18.8.2016	Viekirax	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/14/982	22.8.2016
22.8.2016	Brimica Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/963	24.8.2016
22.8.2016	Dificlir	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/11/733	24.8.2016
22.8.2016	Duaklir Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/964	24.8.2016
22.8.2016	Lumark	IDB Holland B.V. Weverstraat 17, 5111 PV Baarle-Nassau, Nederland	EU/1/15/1013	24.8.2016
22.8.2016	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/767	24.8.2016
22.8.2016	Tasmar	Meda AB Pipers väg 2A, S-170 09 Solna, Sverige	EU/1/97/044	24.8.2016
25.8.2016	Iclusig	ARIAD Pharma Ltd Riverbridge House, Guildford Road, Leatherhead, Surrey KT22 9AD, United Kingdom	EU/1/13/839	30.8.2016
25.8.2016	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	29.8.2016
25.8.2016	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389	30.8.2016
25.8.2016	Renvela	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/09/521	29.8.2016

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25.8.2016	Revestive	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/12/787	29.8.2016
25.8.2016	Tasermity	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/14/953	29.8.2016
25.8.2016	VPRIV	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/10/646	29.8.2016
25.8.2016	XALKORI	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/793	30.8.2016
25.8.2016	Zurampic	Grünenthal GmbH Zieglerstrasse 6, D-52078, Aachen, Deutschland	EU/1/15/1080	29.8.2016
31.8.2016	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	EU/1/14/965	2.9.2016
31.8.2016	Renagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/99/123	2.9.2016

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12.8.2016	Sedadex	dexmedetomidine	Le Vet Beheer B.V. Wilgenweg 7, NL-3421 TV Oudewater, Nederland	EU/2/16/198	Solution for injection	QN05CM18	17.8.2016

— **Modification of a marketing authorization** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

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9.8.2016	Recocam	Cross Vetpharm Group, Ltd Broomhill Road, Tallaght Dublin 24, Ireland	EU/2/11/133	11.8.2016
12.8.2016	Metacam	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/97/004	17.8.2016
26.8.2016	Panacur AquaSol	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/11/135	30.8.2016

— **Withdrawal of a marketing authorization** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
22.8.2016	Velactis	Ceva Santé Animale 10 av. de La Ballastière, 33500 Libourne, France	EU/2/15/192	24.8.2016

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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