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 2017 to 31 December 2017

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

(2018/C 030/01)

([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
8.12.2017	Tacforius	tacrolimus	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/17/1244	prolonged release capsule, hard	L04AD02	12.12.2017
18.12.2017	Alecensa	alectinib	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	Capsule, hard	L01XE36	20.12.2017

— **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
8.12.2017	Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech	XBiotech Germany GmbH Lyoner Straße 14, 60528 Frankfurt am Main, Deutschland	—	12.12.2017
18.12.2017	Masipro	AB Science 3 avenue George V, 75008 Paris, France	—	20.12.2017

— **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
1.12.2017	Alecensa	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	5.12.2017
1.12.2017	Hetlioz	Vanda Pharmaceuticals Limited 25 Old Broad Street, level 21a, London EC2N 1HQ, United Kingdom	EU/1/15/1008	5.12.2017
1.12.2017	Jakavi	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/773	5.12.2017
1.12.2017	OCALIVA	Intercept Pharma Ltd 2 Pancras Square, London N1C 4AG, United Kingdom	EU/1/16/1139	5.12.2017
1.12.2017	Thymanax	Servier (Ireland) Industries Limited Gorey Road, Arklow, Co. Wicklow, Ireland	EU/1/08/498	5.12.2017
8.12.2017	Ceplene	Noventia Pharma Srl Via Carlo Pisacane 31, 47121 Forli, Italia	EU/1/08/477	12.12.2017
8.12.2017	Dexdor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/718	12.12.2017
8.12.2017	Esbriet	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/11/667	13.12.2017
8.12.2017	Esmya	Gedeon Richter Plc. Gyömrői út 19-21., 1103 Budapest, Magyarország	EU/1/12/750	12.12.2017

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
8.12.2017	Genvoya	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/15/1061	12.12.2017
8.12.2017	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/677	13.12.2017
8.12.2017	Humira	AbbVie Ltd Abbvie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire SL6 4UB, United Kingdom	EU/1/03/256	12.12.2017
8.12.2017	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383	13.12.2017
8.12.2017	JETREA	ThromboGenics NV Gaston Geenslaan 1, 3001 Leuven, België	EU/1/13/819	12.12.2017
8.12.2017	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	13.12.2017
8.12.2017	Leganto	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	EU/1/11/695	12.12.2017
8.12.2017	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	13.12.2017
8.12.2017	Moventig	Kyowa Kirin Limited Galabank Business Park, Galashiels, TD1 1QH, United Kingdom	EU/1/14/962	12.12.2017
8.12.2017	Mysimba	Orexigen Therapeutics Ireland Limited 2nd Floor, Palmerston House, Fenian Street, Dublin 2, Ireland	EU/1/14/988	12.12.2017
8.12.2017	Oncaspar	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/15/1070	14.12.2017
8.12.2017	Perjeta	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/813	13.12.2017
8.12.2017	Selincro	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/12/815	12.12.2017
8.12.2017	Taltz	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1085	12.12.2017

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
8.12.2017	Tesavel	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435	13.12.2017
8.12.2017	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1126	12.12.2017
8.12.2017	Xiapex	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/11/671	12.12.2017
8.12.2017	Zevalin	Spectrum Pharmaceuticals B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	EU/1/03/264	12.12.2017
11.12.2017	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1025	13.12.2017
11.12.2017	Holoclar	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/987	13.12.2017
11.12.2017	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/331	13.12.2017
11.12.2017	Odefsey	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/16/1112	13.12.2017
11.12.2017	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	15.12.2017
11.12.2017	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267	13.12.2017
11.12.2017	Strensiq	Alexion Europe SAS 1-15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	EU/1/15/1015	13.12.2017
11.12.2017	Tarceva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/05/311	13.12.2017
11.12.2017	Zyclara	Meda AB Pipers väg 2A, 170 73 Solna, Sverige	EU/1/12/783	13.12.2017

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
15.12.2017	Actelsar HCT	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/13/817	19.12.2017
15.12.2017	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	19.12.2017
15.12.2017	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	19.12.2017
15.12.2017	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	19.12.2017
15.12.2017	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	19.12.2017
15.12.2017	M-M-RVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/337	19.12.2017
15.12.2017	Procysbi	Chiesi Orphan B.V. Graadt van Roggenweg 340, 3531 AH Utrecht, Nederland	EU/1/13/861	19.12.2017
15.12.2017	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	19.12.2017
15.12.2017	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	19.12.2017
15.12.2017	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111	19.12.2017
15.12.2017	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110	19.12.2017
15.12.2017	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	19.12.2017
18.12.2017	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/14/939	20.12.2017
18.12.2017	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/126	20.12.2017

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
18.12.2017	HBVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/01/183	20.12.2017
18.12.2017	NovoMix	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/00/142	20.12.2017
18.12.2017	ProQuad	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/05/323	20.12.2017
18.12.2017	Xelevia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382	20.12.2017
20.12.2017	Azilect	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/04/304	22.12.2017
20.12.2017	Duloxetine Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/972	22.12.2017
20.12.2017	Ebymect	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1051	22.12.2017
20.12.2017	Efient	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/08/503	22.12.2017
20.12.2017	Fabrazyme	Genzyme Europe B.V. Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/01/188	22.12.2017
20.12.2017	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	22.12.2017
20.12.2017	Incresync	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/13/842	20.12.2017
20.12.2017	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/06/368	2.1.2018
20.12.2017	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/11/702	22.12.2017
20.12.2017	Levetiracetam SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/11/741	22.12.2017
20.12.2017	Qtern	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1108	22.12.2017
20.12.2017	Ranexa	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/08/462	22.12.2017
20.12.2017	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/13/892	22.12.2017
20.12.2017	Xigduo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/900	22.12.2017

— **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
1.12.2017	Rabitec	Rabies vaccine (live, oral) for foxes and raccoon dogs	IDT Biologika GmbH Am Pharmapark, 06861 Dessau-Rosslau, Deutschland	EU/2/17/219	Oral suspension	QI07BD	5.12.2017

— **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
6.12.2017	Kexxtone	Eli Lilly and Company Limited Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/12/145	8.12.2017
6.12.2017	Spironolactone Ceva	Ceva Santé Animale 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/07/074	8.12.2017
18.12.2017	Sedadex	Le Vet Beheer B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/16/198	20.12.2017
20.12.2017	Easotic	VIRBAC S.A. 1ère Avenue — 2065 m — L.I.D., 06516 Carros Cedex, France	EU/2/08/085	22.12.2017
20.12.2017	Leucogen	Virbac 1ère Avenue — 2065 m — L.I.D., 06516 Carros Cedex, France	EU/2/09/096	22.12.2017

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

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom