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*(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 April 2017 to 30 April 2017***(Published pursuant to Article 13 or 38 of Regulation (EC) No 726/2004 of the European Parliament and of the
Council ⁽¹⁾)**(2017/C 171/01)*

⁽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
10.4.2017	Chenodeoxycholic acid sigma-tau	chenodeoxycholic acid	sigma-tau Arzneimittel GmbH Liebherstr. 22, 80538 München, Deutschland	EU/1/16/1110	Capsule, hard	A05AA01	12.4.2017
20.4.2017	Roteas	edoxaban	Daichi Sankyo Europe GmbH Zielstattstrasse 48, D-81379 München, Deutschland	EU/1/16/1152	Film-coated tablet	B01AF03	24.4.2017
20.4.2017	Varuby	rolapitant	TESARO UK LIMITED 55 Baker Street, London W1U 7EU, United Kingdom	EU/1/17/1180	Film-coated tablet	A04AD14	24.4.2017
24.4.2017	Natpar	parathyroid hormone	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/15/1078	Powder and solution for injection	H05AA03	26.4.2017
24.4.2017	Pemetrexed Hospira UK Limited	pemetrexed	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/17/1183	Powder for concentrate for solution for infusion	L01BA04	26.4.2017
24.4.2017	TAGRISSO	osimertinib	AstraZeneca AB Gärtunavägen, SE-151 85 Södertälje, Sverige	EU/1/16/1086	Film-coated tablet	L01XE35	26.4.2017
28.4.2017	Darzalex	daratumumab	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/16/1101	Concentrate for solution for infusion	L01XC24	3.5.2017
28.4.2017	Emtricitabine/Tenofovir disoproxil Krka d.d.	emtricitabine/tenofovir disoproxil	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1182	Film-coated tablet	J05AR03	3.5.2017

— **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
3.4.2017	Clopidogrel Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/08/465	5.4.2017
3.4.2017	Corlentor	Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France	EU/1/05/317	5.4.2017
3.4.2017	DuoPlavin	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/10/619	5.4.2017
3.4.2017	JEV TANA	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/11/676	5.4.2017
3.4.2017	Procoralan	Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France	EU/1/05/316	5.4.2017
3.4.2017	Vepacel	Nanotherapeutics UK Limited 10 Chiswell Street, 2nd Floor London, EC1Y 4UQ, United Kingdom	EU/1/12/752	5.4.2017
3.4.2017	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	5.4.2017
6.4.2017	Evra	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/02/223	10.4.2017
6.4.2017	Fycompa	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/12/776	10.4.2017
6.4.2017	Irbesartan Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/576	10.4.2017
6.4.2017	Levetiracetam Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/13/889	10.4.2017
6.4.2017	Vivanza	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/249	10.4.2017
6.4.2017	Zalviso	Grünenthal GmbH Zieglerstrasse 6, D-52078, Aachen, Deutschland	EU/1/15/1042	10.4.2017
11.4.2017	Abasaglar	Eli Lilly Regional Operations GmbH. Kölbgasse 8-10, 1030 Wien, Österreich	EU/1/14/944	13.4.2017
11.4.2017	Constella	Allergan Pharmaceuticals International Limited Clonsaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/12/801	13.4.2017

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
11.4.2017	Envarsus	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/14/935	13.4.2017
11.4.2017	Helixate NexGen	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/00/144	13.4.2017
11.4.2017	Hexacima	Sanofi Pasteur SA 2 avenue Pont Pasteur, F-69007 Lyon, France	EU/1/13/828	13.4.2017
11.4.2017	Iblias	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/15/1077	13.4.2017
11.4.2017	KOGENATE Bayer	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/00/143	13.4.2017
11.4.2017	Kovaltry	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/15/1076	13.4.2017
11.4.2017	Optimark	Guerbet 15, rue des Vanesses, 93420, Villepinte, France	EU/1/07/398	13.4.2017
11.4.2017	Orgalutran	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/130	13.4.2017
11.4.2017	Sylvant	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/928	13.4.2017
12.4.2017	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	19.4.2017
12.4.2017	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	19.4.2017
12.4.2017	Ovaleap	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/13/871	19.4.2017
12.4.2017	Tecfidera	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/13/837	19.4.2017
20.4.2017	Bretaris Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/781	24.4.2017
20.4.2017	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	24.4.2017
20.4.2017	Cetrotide	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/99/100	25.4.2017
20.4.2017	Edistride	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/15/1052	24.4.2017

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
20.4.2017	Eklira Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/778	24.4.2017
20.4.2017	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	24.4.2017
20.4.2017	Glybera	uniQure biopharma B.V. Meibergdreef 61, NL-1105 BA Amsterdam, Nederland	EU/1/12/791	24.4.2017
20.4.2017	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/13/884	24.4.2017
20.4.2017	Izba	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/13/905	24.4.2017
20.4.2017	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	24.4.2017
20.4.2017	Lonquex	UAB 'Sicor Biotech' Molėtų pl. 5, LT-08409 Vilnius, Lietuva	EU/1/13/856	24.4.2017
20.4.2017	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	24.4.2017
20.4.2017	Pandemic influenza vaccine H5N1 MedImmune	MedImmune, LLC Lagelandseweg 78, NL-6545 CG Nijmegen, Nederland	EU/1/16/1089	24.4.2017
20.4.2017	Picato	LEO Laboratories Ltd. 285 Cashel Road, Crumlin, Dublin 12, Ireland	EU/1/12/796	24.4.2017
20.4.2017	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/05/330	24.4.2017
20.4.2017	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	24.4.2017
20.4.2017	Tamiflu	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222	24.4.2017
20.4.2017	Travatan	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/01/199	24.4.2017
20.4.2017	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/918	24.4.2017
20.4.2017	Xigduo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/900	24.4.2017

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
24.4.2017	CANCIDAS	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/01/196	26.4.2017
24.4.2017	Darzalex	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/16/1101	26.4.2017
24.4.2017	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony CEDEX, France	EU/1/07/384	26.4.2017
24.4.2017	Esbriet	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/11/667	26.4.2017
24.4.2017	Flebogamma DIF	Instituto Grifols, S.A. Can Guasch 2, Parets del Vallès, E-08150 Barcelona, España	EU/1/07/404	26.4.2017
24.4.2017	Imatinib Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/13/825	26.4.2017
24.4.2017	Jakavi	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/773	26.4.2017
24.4.2017	Opatanol	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/02/217	26.4.2017
24.4.2017	Siklos	Addmedica 101 rue Saint Lazare, F-75009 Paris, France	EU/1/07/397	26.4.2017
24.4.2017	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/785	26.4.2017
28.4.2017	Actos	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/00/150	3.5.2017
28.4.2017	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268	3.5.2017
28.4.2017	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	4.5.2017
28.4.2017	Cinqaero	Teva Pharmaceuticals Limited Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX, United Kingdom	EU/1/16/1125	3.5.2017
28.4.2017	CONTROLOC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/515	3.5.2017

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
28.4.2017	Fertavid	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/510	3.5.2017
28.4.2017	Glustin	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/00/151	3.5.2017
28.4.2017	Imatinib Medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6, D-22880 Wedel, Deutschland	EU/1/13/876	3.5.2017
28.4.2017	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/13/884	3.5.2017
28.4.2017	Ixiaro	Valneva Austria GmbH Campus Vienna Biocenter 3, A-1030 Wien, Österreich	EU/1/08/501	3.5.2017
28.4.2017	Kalydeco	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/12/782	3.5.2017
28.4.2017	NovoNorm	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/98/076	3.5.2017
28.4.2017	Opdivo	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1014	3.5.2017
28.4.2017	PANTOLOC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/519	3.5.2017
28.4.2017	PANTOZOL Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/517	3.5.2017
28.4.2017	Prandin	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/00/162	3.5.2017
28.4.2017	Puregon	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/008	3.5.2017
28.4.2017	Repaglinide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/530	3.5.2017
28.4.2017	SOMAC Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/516	3.5.2017
28.4.2017	Temozolomide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/606	3.5.2017

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
28.4.2017	Tresiba	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/12/807	3.5.2017
28.4.2017	Trobalt	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/11/681	3.5.2017
28.4.2017	Vizarsin	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/551	3.5.2017
28.4.2017	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/918	3.5.2017
28.4.2017	Xeplion	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/672	3.5.2017
28.4.2017	Zebinix	Bial-Portela & C ^a , SA À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/09/514	3.5.2017
28.4.2017	Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6, D-22880 Wedel, Deutschland	EU/1/12/779	3.5.2017

— **Withdrawal of a marketing authorisation** (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 authorisation	Number of the entry in the Community Register	Date of notification
3.4.2017	Imprida	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/373	5.4.2017
24.4.2017	DUTREBIS	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/995	26.4.2017

— **Issuing 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	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
25.4.2017	Credelio	lotilaner	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/17/206	Chewable tablet	QP53BE04	27.4.2017
25.4.2017	CYTOPOINT	lokivetmab	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/205	solution for injection in a vial	QD11AH91	27.4.2017
25.4.2017	Zulvac BTV Ovis	Bluetongue vaccine (inactivated): serotype 1, 4, 8	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/207	Suspension for injection	QI04AA02	27.4.2017

— **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
11.4.2017	Procox	Bayer Animal Health GmbH D-51368 Leverkusen, Deutschland	EU/2/11/123	19.4.2017
12.4.2017	FORTEKOR PLUS	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/15/185	19.4.2017
25.4.2017	Cerenia	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/06/062	27.4.2017
25.4.2017	Quadrisol	VETCOOL B.V. Otto Hahnweg 24, 3542 AX Utrecht, Nederland	EU/2/97/005	28.4.2017

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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