

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 July 2017 to 31 August 2017***(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 328/01)

⁽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
6.7.2017	OXERVATE	cenegermin	Dompé farmaceutici S.p.A. Via Santa Lucia 6, 20122 Milano, Italia	EU/1/17/1197	Eye drops, solution	Pending	10.7.2017
10.7.2017	Spherox	spheroids of human autologous matrix-associated chondrocytes	CO.DON AG Warthestraße 21, 14513 Teltow, Deutschland	EU/1/17/1181	Implantation suspension	M09AX02	12.7.2017
13.7.2017	Blitzima	rituximab	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1205	Concentrate for solution for infusion	L01XC02	17.7.2017
13.7.2017	Reagila	cariprazine	Gedeon Richter Plc. Gyömrői út 19-21., H-1103 Budapest, Magyarország	EU/1/17/1209	Capsule, hard	N05AX15	17.7.2017
13.7.2017	Ritemvia	rituximab	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1207	Concentrate for solution for infusion	L01XC02	17.7.2017
13.7.2017	Tuxella	rituximab	Celltrion Healthcare Hungary Kft. 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/17/1206	Concentrate for solution for infusion	L01XC02	17.7.2017
17.7.2017	Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva	efavirenz/emtricitabine/tenofovir disoproxil	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/17/1210	Film-coated tablet	J05AR06	19.7.2017
17.7.2017	Kyntheum	brodalumab	Leo Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/16/1155	Solution for injection	L04AC12	19.7.2017

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17.7.2017	Trimbow	beclometasone/formoterol/glycopyrronium bromide	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/17/1208	Pressurised inhalation, solution	R03AL09	19.7.2017
19.7.2017	Insulin lispro Sanofi	insulin lispro	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/17/1203	Solution for injection	A10AB04	21.7.2017
19.7.2017	Veltassa	patiromer	Vifor Fresenius Medical Care Renal Pharma France 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/17/1179	Powder for oral suspension	V03AE09	21.7.2017
26.7.2017	Maviret	glecaprevir/pibrentasvir	AbbVie Ltd M Maidenhead, SL6 4UB, United Kingdom	EU/1/17/1213	Film-coated tablet	J05AX	28.7.2017
26.7.2017	Vosevi	sofosbuvir/velpatasvir/voxilaprevir	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/17/1223	Film-coated tablet	Pending	28.7.2017
26.7.2017	Zykadia	ceritinib	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/999	Capsule, hard	L01XE28	28.7.2017
22.8.2017	Kisqali	ribociclib	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/17/1221	Film-coated tablet	L01XE42	24.8.2017
22.8.2017	MAVENCLAD	cladribine	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/17/1212	Tablet	L01BB04	24.8.2017

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24.8.2017	Fotivda	tivozanib	EUSA Pharma (UK) Limited Breakspear Park, Breakspear Way, HP2 4TZ, Hemel Hempstead, United Kingdom	EU/1/17/1215	Capsule, hard	L01XE34	29.8.2017
24.8.2017	Imraldi	adalimumab	Samsung Bioepis UK Limited 5th floor, Profile West, 950 Great West Road, Brentford, Middlesex TW8 9ES, United Kingdom	EU/1/17/1216	Solution for injection	L04AB04	29.8.2017
24.8.2017	Nitisinone Mendell-KABS	nitisinone	MendellKABS Europe Limited Office 7, Gateway 1000, Whittle Way, Stevenage, Hertfordshire, SG1 2FP, United Kingdom	EU/1/17/1217	Capsule, hard	A16AX04	29.8.2017

— **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
6.7.2017	Celsentri	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/07/418	10.7.2017
6.7.2017	Clopidogrel Krka d. d.	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	10.7.2017
6.7.2017	Imlygic	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1064	10.7.2017
6.7.2017	Kivexa	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/298	10.7.2017
6.7.2017	Nexavar	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/06/342	10.7.2017
6.7.2017	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386	10.7.2017
10.7.2017	Memantine Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/880	12.7.2017
10.7.2017	Myozyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/06/333	12.7.2017
10.7.2017	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	12.7.2017
13.7.2017	Edistride	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/15/1052	17.7.2017
13.7.2017	Enurev Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/789	17.7.2017
13.7.2017	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	17.7.2017
13.7.2017	Incruse	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/922	17.7.2017
13.7.2017	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436	17.7.2017

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
13.7.2017	Kuvan	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, Ireland	EU/1/08/481	17.7.2017
13.7.2017	Latuda	Sunovion Pharmaceuticals Europe Ltd First Floor, Southside, 97-105 Victoria Street, London SW1E 6QT, United Kingdom	EU/1/14/913	17.7.2017
13.7.2017	Lixiana	Daiichi Sankyo Europe GmbH Zielstattstrasse 48, D-81379 München, Deutschland	EU/1/15/993	17.7.2017
13.7.2017	Memantine Merz	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/12/799	17.7.2017
13.7.2017	Picato	LEO Laboratories Ltd. 285 Cashel Road, Crumlin, Dublin 12, Ireland	EU/1/12/796	17.7.2017
13.7.2017	Praxbind	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1056	17.7.2017
13.7.2017	Torisel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/424	17.7.2017
13.7.2017	Xaluprine	Nova Laboratories Limited Martin House, Gloucester Crescent, Wigston Leicester, LE18 4YL, United Kingdom	EU/1/11/727	17.7.2017
13.7.2017	Xultophy	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/14/947	17.7.2017
13.7.2017	Zalmoxis	MolMed S.p.A. Via Olgettina 58, I-20132 Milano, Italia	EU/1/16/1121	17.7.2017
13.7.2017	Zoledronic acid Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/834	17.7.2017
14.7.2017	Zinbryta	Biogen Idec Limited Innovation House, 70 Norden Road, Maiden- head, Berkshire SL6 4AY, United Kingdom	EU/1/16/1107	18.7.2017
17.7.2017	Dinutuximab beta Apeiron	EUSA Pharma (UK) Limited Breakspear Park, Breakspear Way, HP2 4TZ, Hemel Hempstead, United Kingdom	EU/1/17/1191	19.7.2017
17.7.2017	Inhixa	Techdow Europe AB Kåbovägen 32, 75236 Uppsala, Sverige	EU/1/16/1132	20.7.2017
17.7.2017	Opsumit	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/13/893	19.7.2017

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
17.7.2017	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/09/599	19.7.2017
17.7.2017	Thorinane	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077XX Amsterdam, Nederland	EU/1/16/1131	19.7.2017
17.7.2017	Zinfo	Pfizer Ireland Pharmaceuticals Operations Services Group, Ringaskiddy, County Cork, Ireland	EU/1/12/785	19.7.2017
19.7.2017	Clopidogrel BGR	Laboratoires BIOGARAN 15 boulevard Charles de Gaulle, 92707 Co- lombes Cedex, France	EU/1/09/558	21.7.2017
19.7.2017	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	21.7.2017
19.7.2017	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, D-27472 Cuxhaven, Deutschland	EU/1/09/555	21.7.2017
19.7.2017	Cuprymina	SPARKLE S.r.l. Località Cavallino, 62010 Montecosaro (MC), Italia	EU/1/12/784	24.7.2017
19.7.2017	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	24.7.2017
19.7.2017	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	21.7.2017
19.7.2017	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/958	24.7.2017
19.7.2017	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	21.7.2017
19.7.2017	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	21.7.2017
19.7.2017	Qtern	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1108	24.7.2017
19.7.2017	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Strasse 8, D-79539 Lörrach, Deutschland	EU/1/15/1020	24.7.2017
19.7.2017	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	21.7.2017
19.7.2017	Seebri Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/788	21.7.2017

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19.7.2017	Synjardy	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/15/1003	21.7.2017
19.7.2017	Tracleer	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220	21.7.2017
19.7.2017	Zavesca	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/238	21.7.2017
19.7.2017	Zavicefta	Pfizer Ireland Pharmaceuticals Operations Services Group, Ringaskiddy, County Cork, Ireland	EU/1/16/1109	24.7.2017
25.7.2017	Faslodex	AstraZeneca UK Limited Charter Way, Macclesfield, Cheshire, SK10 2NA, United Kingdom	EU/1/03/269	27.7.2017
25.7.2017	Granupas	Lucane Pharma 172 rue de Charonne, 75011 Paris, France	EU/1/13/896	27.7.2017
25.7.2017	Olanzapine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/08/475	31.7.2017
25.7.2017	Orencia	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/07/389	27.7.2017
25.7.2017	Rivastigmine 1 A Pharma	1 A Pharma GmbH Keltenring 1 + 3, D-82041 Oberhaching, Deutschland	EU/1/09/585	28.7.2017
25.7.2017	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	27.7.2017
25.7.2017	Voncento	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/13/857	28.7.2017
26.7.2017	Aripiprazole Mylan Pharma	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/15/1005	28.7.2017
26.7.2017	Bridion	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/466	28.7.2017
26.7.2017	Kaletra	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	28.7.2017
26.7.2017	Oprymea	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/469	28.7.2017
26.7.2017	Tovanor Breezhaler	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/12/790	28.7.2017

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26.7.2017	Velphoro	Vifor Fresenius Medical Care Renal Pharma France 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/14/943	28.7.2017
26.7.2017	Votubia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/710	28.7.2017
26.7.2017	Yellox	PharmaSwiss Česká republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 Česká republika	EU/1/11/692	28.7.2017
2.8.2017	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	4.8.2017
2.8.2017	Zyllt	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553	4.8.2017
3.8.2017	Abilify	Otsuka Pharmaceutical Europe Ltd. Gallions, Wexham Springs, Framewood Road, Wexham, SL3 6PJ, United Kingdom	EU/1/04/276	17.8.2017
3.8.2017	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285	7.8.2017
7.8.2017	Colobreathe	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/747	9.8.2017
7.8.2017	Nordimet	Nordic Group B.V. Siriusdreef 22, NL-2132 WT Hoofddorp, Nederland	EU/1/16/1124	9.8.2017
7.8.2017	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	9.8.2017
14.8.2017	Exjade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/356	17.8.2017
14.8.2017	Mekinist	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/14/931	18.8.2017
14.8.2017	Soliris	Alexion Europe SAS 1-15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	EU/1/07/393	17.8.2017
14.8.2017	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	17.8.2017

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
14.8.2017	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	17.8.2017
22.8.2017	CoAprovel	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/086	24.8.2017
22.8.2017	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	EU/1/14/965	24.8.2017
22.8.2017	Rasilez	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/07/405	24.8.2017
22.8.2017	SonoVue	Bracco International B.V. Strawinskylaan 3051, NL-1077 ZX Amsterdam, Nederland	EU/1/01/177	24.8.2017
22.8.2017	Xarelto	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/08/472	24.8.2017
24.8.2017	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185	28.8.2017
24.8.2017	BYDUREON	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/696	28.8.2017
24.8.2017	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	28.8.2017
24.8.2017	EDURANT	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/736	28.8.2017
24.8.2017	Fluenz Tetra	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/887	28.8.2017
24.8.2017	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	28.8.2017
24.8.2017	Invega	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/07/395	28.8.2017
24.8.2017	Kaletra	AbbVie Ltd M Maidenhead, SL6 4UB, United Kingdom	EU/1/01/172	29.8.2017
24.8.2017	Karvezide	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/085	28.8.2017
24.8.2017	KEYTRUDA	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	29.8.2017
24.8.2017	Norvir	AbbVie Ltd M Maidenhead, SL6 4UB, United Kingdom	EU/1/96/016	29.8.2017

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
24.8.2017	Orkambi	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/15/1059	29.8.2017
24.8.2017	Ruconest	Pharming Group N.V. Darwinweg 24, NL-2333 CR Leiden, Nederland	EU/1/10/641	28.8.2017
24.8.2017	Zoledronic acid Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/12/800	29.8.2017
28.8.2017	Constella	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/12/801	30.8.2017
28.8.2017	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416	30.8.2017
28.8.2017	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	30.8.2017
28.8.2017	Irbesartan HCT Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/06/377	30.8.2017
28.8.2017	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292	30.8.2017
28.8.2017	Rasilez HCT	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/08/491	30.8.2017

— **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
19.7.2017	Enzeppi	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1113	21.7.2017
19.7.2017	Repso	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/674	21.7.2017

— **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
17.8.2017	VEPURED	<i>E. coli</i> verotoxoid vaccine (inactivated recombinant)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/17/214	Suspension for injection	QI09AB02	21.8.2017
18.8.2017	Exzolt	fluralaner	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/17/212	Solution for use in drinking water	QP53BE02	22.8.2017
22.8.2017	Innovax-ND-IBD	Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/17/213	Suspension and solvent for suspension for injection	QI01AD	24.8.2017
24.8.2017	Suvaxyn PRRS MLV	Porcine respiratory and reproductive syndrome virus vaccine (live)	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/215	Lyophilisate and solvent for suspension for injection	QI09AD03	28.8.2017

— **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
10.7.2017	Onsior	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/08/089	12.7.2017
14.7.2017	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/14/174	18.7.2017
14.7.2017	Zolvix	Elanco Europe Ltd. Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/09/101	18.7.2017
19.7.2017	Aivlosin	ECO Animal Health Ltd 78 Coombe Road, New Malden, Surrey KT3 4QS United Kingdom	EU/2/04/044	21.7.2017
28.7.2017	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kingdom	EU/2/08/090	1.8.2017
28.7.2017	Vaxxitek HVT + IBD	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/02/032	1.8.2017
3.8.2017	BLUEVAC BTV8	CZ Veterinaria, S.A. La Relva s/n, 36400 Porriño, España	EU/2/11/122	7.8.2017
10.8.2017	Canigen L4	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/15/183	14.8.2017

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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