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 2019 to 31 December 2019

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

(2020/C 33/01)

[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
9.12.2019	Evenity	romosozumab	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/19/1411	Solution for injection	M05BX	11.12.2019
16.12.2019	Baqsimi	Glucagon	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/19/1406	nasal powder	H04AA01	18.12.2019
16.12.2019	Quofenix	delafloxacin	A. Menarini — Industrie Farmaceutiche Riunite — s.r.l. Via Sette Santi 3, 50131 Florence, Italia	EU/1/19/1393	Powder for concentrate for solution for infusion Tablet	J01MA23	19.12.2019
16.12.2019	Rinvoq	upadacitinib	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	Prolonged-release tablet	L04AA	18.12.2019
18.12.2019	Spravato	esketamine	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	Nasal spray, solution	N06AX27	20.12.2019
19.12.2019	Pegfilgrastim Mundipharma	pegfilgrastim	Mundipharma Biologics S.L. Calle García Ximénez, nº3-1º, 31002 Pamplona (Navarra), España	EU/1/19/1409	Solution for injection	L03AA13	23.12.2019

— **Issuing of a marketing authorisation** (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 authorisation	Number of the entry in the Community Register	Date of notification
19.12.2019	Vanflyta	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	—	23.12.2019

— **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
5.12.2019	AUBAGIO	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/13/838	9.12.2019
5.12.2019	CANCIDAS	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/01/196	9.12.2019
5.12.2019	Cerezyme	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/97/053	10.12.2019
5.12.2019	Kanuma	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1033	9.12.2019
5.12.2019	Nexium Control	Pfizer Healthcare Ireland 9 Riverwalk National Digital Park, Citywest Business Campus, Dublin 24, D24 NT20, Ireland	EU/1/13/860	9.12.2019
5.12.2019	Orfadin	Swedish Orphan Biovitrum International AB 112 76 Stockholm, Sverige	EU/1/04/303	10.12.2019
5.12.2019	Topotecan Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/10/633	9.12.2019
5.12.2019	Xydalba	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland	EU/1/14/986	9.12.2019
9.12.2019	Emgality	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1330	11.12.2019
9.12.2019	Evra	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/02/223	11.12.2019

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
9.12.2019	Grastofil	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/877	11.12.2019
9.12.2019	Jinarc	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Noord-Holland, Nederland	EU/1/15/1000	11.12.2019
9.12.2019	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited 28-32 Pembroke Street Upper, Dublin 2, D02 EK84, Ireland	EU/1/12/782	11.12.2019
9.12.2019	Levitra	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/248	11.12.2019
9.12.2019	Pazenir	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/18/1317	12.12.2019
9.12.2019	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/15/992	11.12.2019
9.12.2019	Torisel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/07/424	11.12.2019
9.12.2019	Vivanza	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/249	11.12.2019
9.12.2019	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	11.12.2019
10.12.2019	Cinqaero	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/16/1125	11.12.2019
16.12.2019	Cerdelga	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/14/974	18.12.2019
16.12.2019	CRYSVITA	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	18.12.2019
16.12.2019	CRYSVITA	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	18.12.2019

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
16.12.2019	Darunavir Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/16/1140	18.12.2019
16.12.2019	Feraccru	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/15/1075	18.12.2019
16.12.2019	Firmagon	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, 2300 Copenhagen S, Danmark	EU/1/08/504	18.12.2019
16.12.2019	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	18.12.2019
16.12.2019	INCRELEX	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/07/402	18.12.2019
16.12.2019	Ivemend	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/437	18.12.2019
16.12.2019	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	18.12.2019
16.12.2019	Kengrexal	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/15/994	18.12.2019
16.12.2019	Kolbam	Retrophin Europe Limited Palmerston House, Fenian Street, Dublin 2, Ireland	EU/1/13/895	18.12.2019
16.12.2019	Kromeya	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/19/1357	19.12.2019
16.12.2019	Lamivudine Teva Pharma B.V.	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/596	18.12.2019
16.12.2019	Mepact	Takeda France SAS Immeuble Pacific, 11-13 cours Valmy, 92800 Puteaux, France	EU/1/08/502	18.12.2019
16.12.2019	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	19.12.2019

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
16.12.2019	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	19.12.2019
16.12.2019	Pregabalin Zentiva k.s	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1166	18.12.2019
16.12.2019	Relistor	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/08/463	18.12.2019
16.12.2019	Relvar Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/13/886	18.12.2019
16.12.2019	Revinty Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/929	18.12.2019
16.12.2019	Rizmoic	Shionogi B.V. Kingsfordweg 151, 1043GR Amsterdam, Nederland	EU/1/18/1291	18.12.2019
16.12.2019	Xeljanz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/17/1178	18.12.2019
17.12.2019	YERVOY	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/698	19.12.2019
18.12.2019	Darunavir Krka	Krka d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1249	20.12.2019
18.12.2019	Firazyr	Shire Pharmaceuticals Ireland Limited Block 2 & 3 Miesian Plaza, 50-58 Baggot Street Lower, D02 Y754 Dublin 2, Ireland	EU/1/08/461	20.12.2019
18.12.2019	HBVAXPRO	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/01/183	20.12.2019
18.12.2019	Levetiracetam Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/13/889	20.12.2019
18.12.2019	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/08/448	20.12.2019

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
18.12.2019	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/18/1290	23.12.2019
18.12.2019	Orbactiv	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Grand-Duché de Luxembourg	EU/1/15/989	20.12.2019
18.12.2019	PANTOLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/519	20.12.2019
18.12.2019	Prialt	RIEMSER Pharma GmbH An der Wiek 7, 17493 Greifswald-Insel Riems, Deutschland	EU/1/04/302	20.12.2019
18.12.2019	Revlimid	Celgene Europe B.V. Winthontlaan 6 N, 3526 KV Utrecht, Nederland	EU/1/07/391	20.12.2019
18.12.2019	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	20.12.2019
18.12.2019	Roteas	Berlin-Chemie AG Glienicker Weg 125, 12489 Berlin, Deutschland	EU/1/16/1152	20.12.2019
18.12.2019	Yentreve	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/280	20.12.2019

— **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
5.12.2019	Xiapex	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/11/671	10.12.2019
16.12.2019	Helixate NexGen	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/00/144	18.12.2019
17.12.2019	Kromeya	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/19/1357	19.12.2019

— **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
10.12.2019	Mirataz	mirtazapine	Aniserve GmbH Geyersperger Str. 27, 80689 Munich, Deutschland	EU/2/19/247	Transdermal ointment	QN06AX11	12.12.2019
10.12.2019	Neptra	florfenicol/ terbinafine hydrochloride/ mometasone furoate	Bayer Animal Health GmbH D-51368 Leverkusen, Deutschland	EU/2/19/246	Ear drops, solution	QS02CA91	12.12.2019

— **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
10.12.2019	Eurican Herpes 205	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/01/029	12.12.2019
10.12.2019	Stronghold	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/99/014	12.12.2019
16.12.2019	Afoxolaner MERIAL	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/19/240	19.12.2019
16.12.2019	Previcox	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/045	19.12.2019
16.12.2019	Purevax FeLV	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/00/019	19.12.2019
16.12.2019	Purevax RCP	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/052	19.12.2019
16.12.2019	Purevax RCPCh	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/050	19.12.2019
16.12.2019	Purevax RCPCh FeLV	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/047	19.12.2019
17.12.2019	Aftovaxpur Doe	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/13/153	19.12.2019
17.12.2019	BROADLINE	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/13/157	19.12.2019
17.12.2019	GALLIPRANT	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/221	19.12.2019
17.12.2019	NexGard	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/2/13/159	19.12.2019
17.12.2019	NEXGARD SPECTRA	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/2/14/177	19.12.2019

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
17.12.2019	Oncept IL-2	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/13/150	19.12.2019
17.12.2019	Purevax RC	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/051	19.12.2019
17.12.2019	Purevax RCP FeLV	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/048	19.12.2019
19.12.2019	Bravecto Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/18/224	2.1.2020
19.12.2019	Neocolipor	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/98/008	23.12.2019
19.12.2019	Vaxxitek HVT + IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/02/032	23.12.2019
19.12.2019	Zactran	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/08/082	23.12.2019

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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