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 2020 to 31 December 2020

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

(2021/C 33/01)

[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
9.12.2020	Leqvio	inclisiran	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1494	Solution for injection	C10AX16	10.12.2020
9.12.2020	TRIXEO AEROSPHERE	Formoterol / glycopyrronium bromide / budesonide	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1498	Pressurised inhalation, suspension	R03AL11	10.12.2020
14.12.2020	Tecartus	autologous anti-CD19-transduced CD3+ cells	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	Dispersion for infusion	L01X	15.12.2020
17.12.2020	Libmeldy	autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene	Orchard Therapeutics (Netherlands) B.V. Prins Bernhardplein 200, 1097 JB, Noord-Holland, Amsterdam, Nederland	EU/1/20/1493	Dispersion for infusion	Pending	18.12.2020

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
17.12.2020	REKAMBYS	rilpivirine	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1482	Prolonged release suspension for injection	J05AG05	21.12.2020
17.12.2020	Vocabria	cabotegravir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	Film-coated tablet Prolonged release suspension for injection	J05AJ04	21.12.2020
18.12.2020	Fintepla	fenfluramine	Zogenix ROI Limited Trinity House, Charleston Road, Ranelagh, Dublin 6, D06 C8X4, Ireland	EU/1/20/1491	Oral solution	N03AX	21.12.2020
18.12.2020	Lenalidomide Mylan	lenalidomide	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1490	Capsule, hard	L04AX04	21.12.2020
21.12.2020	Phesgo	pertuzumab / trastuzumab	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1497	Solution for injection	L01XY02	22.12.2020

— **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
1.12.2020	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/08/470	2.12.2020
1.12.2020	Zonisamide Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/16/1093	4.12.2020
9.12.2020	Aldara	Meda AB Pipers väg 2A, 170 73 Solna, Sverige	EU/1/98/080	11.12.2020
9.12.2020	Caspofungin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/15/1081	11.12.2020
9.12.2020	Epidyolex	GW Pharma (International) B.V. Databankweg 26, 3821AL Amersfoort, Nederland	EU/1/19/1389	11.12.2020
9.12.2020	Inlyta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/777	11.12.2020
9.12.2020	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	10.12.2020
9.12.2020	Lucentis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/374	10.12.2020
9.12.2020	MAVENCLAD	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/17/1212	11.1.2021
9.12.2020	Miglustat Dipharma	Dipharma B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	EU/1/18/1346	10.12.2020
9.12.2020	Neofordex	Laboratoires CTRS 63 rue de l'Est, 92100 Boulogne-Billancourt, France	EU/1/15/1053	11.12.2020
9.12.2020	Olazax Disperzi	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b, 14078 Praha 4, Česká republika	EU/1/09/592	11.12.2020
9.12.2020	Onbrez Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/593	10.12.2020
9.12.2020	Orbactiv	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/989	10.12.2020

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
9.12.2020	Orencia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/389	10.12.2020
9.12.2020	Polivy	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/19/1388	10.12.2020
9.12.2020	SCENESSE	Clinuvel Europe Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/14/969	10.12.2020
9.12.2020	Seebri Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/788	10.12.2020
9.12.2020	Tovanor Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/790	6.1.2021
14.12.2020	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/12/794	15.12.2020
14.12.2020	Bosulif	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/818	15.12.2020
14.12.2020	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	15.12.2020
14.12.2020	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	17.12.2020
14.12.2020	Jakavi	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/773	17.12.2020
14.12.2020	JEVTANA	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/11/676	17.12.2020
14.12.2020	Lonsurf	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France	EU/1/16/1096	15.12.2020
14.12.2020	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	15.12.2020
14.12.2020	Revatio	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/05/318	21.12.2020
14.12.2020	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	16.12.2020

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
14.12.2020	Zyclara	Meda AB Pipers väg 2A, 170 73 Solna, Sverige	EU/1/12/783	17.12.2020
17.12.2020	Empliciti	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/16/1088	19.12.2020
17.12.2020	Halimatoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1288	7.1.2021
17.12.2020	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	21.12.2020
17.12.2020	Kyprolis	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1060	18.12.2020
17.12.2020	Lorviqua	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	18.12.2020
17.12.2020	Rubraca	Clovis Oncology Ireland Limited Regus Dublin Airport, Skybridge House — Dublin Airport, Swords, Co. Dublin, K67 P6K2, Ireland	EU/1/17/1250	21.12.2020
17.12.2020	Taltz	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1085	22.12.2020
17.12.2020	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland	EU/1/16/1126	30.12.2020
17.12.2020	Verzenios	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1307	22.12.2020
17.12.2020	Votrient	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/628	20.12.2020
17.12.2020	Wakix	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/15/1068	6.1.2021
17.12.2020	Xyrem	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/312	18.12.2020
17.12.2020	Ziextenzo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1327	7.1.2021
18.12.2020	Cerezyme	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/97/053	21.12.2020

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
18.12.2020	Galvus	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/414	6.1.2021
18.12.2020	Jalra	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/485	6.1.2021
18.12.2020	Jivi	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/18/1324	22.12.2020
18.12.2020	Pixuvri	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes Cedex, France	EU/1/12/764	22.12.2020
18.12.2020	Rixubis	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/14/970	22.12.2020
18.12.2020	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	21.12.2020
18.12.2020	Xiliarx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/486	6.1.2021
21.12.2020	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	22.12.2020
22.12.2020	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	25.12.2020
22.12.2020	Zirabev	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1344	23.12.2020

— **Withdrawal of a marketing authorization** (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 authorization	Number of the entry in the Community Register	Date of notification
17.12.2020	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/453	4.1.2021
18.12.2020	Halimatoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1288	8.1.2021
18.12.2020	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland	EU/1/16/1126	5.1.2021

— **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
3.12.2020	REXXOLIDE	tulathromycin	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/20/263	Solution for injection	QJ01FA94	9.12.2020
9.12.2020	CircoMax Myco	Porcine circovirus vaccine (inactivated, recombinant) and Mycoplasma hyopneumoniae vaccine (inactivated)	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/264	Emulsion for injection	QI09AL08	11.12.2020
9.12.2020	Enteroporc Coli AC	Neonatal piglet colibacillosis (recombinant, inactivated) and Clostridium perfringens vaccine (inactivated)	IDT Biologika GmbH Am Pharmapark, 06861 Dessau-Rosslau, Deutschland	EU/2/20/262	Lyophilisate and suspension for suspension for injection	Pending	10.12.2020
9.12.2020	Nobivac DP Plus	Canine distemper vaccine (live) and canine parvovirus vaccine (live, recombinant)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/20/265	Lyophilisate and solvent for suspension for injection	QI07AD03	10.12.2020

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
9.12.2020	Vectormune FP ILT	Fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant)	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/20/266	Lyophilisate and solvent for suspension for injection	Pending	10.12.2020

— **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
3.12.2020	Bravecto Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/18/224	4.12.2020
3.12.2020	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	4.12.2020
9.12.2020	Bravecto	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/13/158	10.12.2020
9.12.2020	Circovac	Ceva-Phylaxia Zrt. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/07/075	11.12.2020
9.12.2020	Zulvac SBV	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/178	11.12.2020
11.12.2020	Onsior	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/08/089	14.12.2020
17.12.2020	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/98/006	21.12.2020

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
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS