Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2020 to 31 May 2020

(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 213/02)

[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
18.5.2020	Zolgensma	onasemnogene abeparvovec	AveXis EU Limited Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland	EU/1/20/1443	Solution for infusion	M09AX09	18.5.2020
20.5.2020	Fluad Tetra	influenza vaccine (surface antigen, inactivated, adjuvanted)	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Netherlands	EU/1/20/1433	Suspension for injection in pre-filled syringe (injection).	J07BB02	26.5.2020
20.5.2020	Nepexto	etanercept	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13 Ireland	EU/1/20/1436	Solution for injection	L04AB01	29.5.2020
30.5.2020	Atectura Breezhaler	indacaterol/mometasone furoate	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1439	Inhalation powder, hard capsule	R03AK14	2.6.2020
30.5.2020	Bemrist Breezhaler	indacaterol/mometasone furoate	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1441	Inhalation powder, hard capsule	R03AK	2.6.2020
30.5.2020	Sarclisa	isatuximab	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/20/1435	Concentrate for solution for infusion	L01XC38	3.6.2020

— **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
4.5.2020	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/02/218	8.5.2020
4.5.2020	Bortezomib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/15/1019	12.5.2020
4.5.2020	Bronchitol	Pharmaxis Europe Limited 108 Q House, Furze Road, Sandyford Dublin 18, D18AY29, Ireland	EU/1/12/760	5.5.2020
4.5.2020	Clopidogrel Apotex	Apotex Europe B.V. Archimedesweg 2, 2333 CN Leiden, Nederland	EU/1/09/568	6.5.2020
4.5.2020	Clopidogrel Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/09/559	5.5.2020
4.5.2020	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	7.5.2020
4.5.2020	Cystadrops	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/15/1049	6.5.2020
4.5.2020	Ferriprox	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/99/108	7.5.2020
4.5.2020	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	5.5.2020
4.5.2020	Ilumetri	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/18/1323	5.5.2020
4.5.2020	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	12.5.2020
4.5.2020	Pemetrexed medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/15/1038	12.5.2020
4.5.2020	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Straße 8, 79539 Lörrach, Deutschland	EU/1/15/1020	14.5.2020
4.5.2020	Tafinlar	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/865	8.5.2020
4.5.2020	Wilzin	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/04/286	5.5.2020
4.5.2020	Xultophy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/14/947	6.5.2020

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5.5.2020	Naglazyme	BioMarin International Limited Shanbally, Ringaskiddy, County Cork P43 R298, Ireland	EU/1/05/324	6.5.2020
12.5.2020	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	19.5.2020
12.5.2020	Clopidogrel Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	13.5.2020
12.5.2020	Movymia	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/16/1161	13.5.2020
12.5.2020	Pemetrexed Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/15/1057	14.5.2020
12.5.2020	Segluromet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1265	14.5.2020
12.5.2020	Steglatro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1267	14.5.2020
12.5.2020	Steglujan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1266	14.5.2020
12.5.2020	Vedrop	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/09/533	13.5.2020
14.5.2020	Clopidogrel Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	18.5.2020
14.5.2020	Firdapse	SERB S.A. Avenue Louise 480, 1050 Bruxelles, Belgique/ Louizalaan 480, 1050 Brussel, België	EU/1/09/601	15.5.2020
14.5.2020	Yellox	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/11/692	15.5.2020
18.5.2020	Signifor	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/12/753	19.5.2020
20.5.2020	Daxas	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/636	28.5.2020
20.5.2020	Ivabradine Anpharm	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A. ul. Annopol 6B, 03–236 Warszawa, Polska	EU/1/15/1041	25.5.2020
20.5.2020	Jorveza	Dr Falk Pharma GmbH Leinenweberstraße 5, 79041 Freiburg im Breisgau, Deutschland	EU/1/17/1254	26.5.2020

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20.5.2020	Lenvima	Eisai GmbH Lyoner Straße 36, 60528 Frankfurt am Main, Deutschland	EU/1/15/1002	26.5.2020
20.5.2020	LIBTAYO	Regeneron Ireland Designated Activity Company (DAC) Europa House, Harcourt Centre, Harcourt Street, Dublin 2, Ireland	EU/1/19/1376	26.5.2020
20.5.2020	Nplate	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/08/497	25.5.2020
20.5.2020	Odomzo	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/15/1030	28.5.2020
20.5.2020	Onpattro	Alnylam Netherlands B.V. Strawinskylaan 3051, 1077 ZX, Amsterdam, Nederland	EU/1/18/1320	25.5.2020
20.5.2020	Pregabalin Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1021	25.5.2020
20.5.2020	Revestive	Shire Pharmaceuticals Ireland Limited Block 2 & 3 Miesian Plaza, 50-58 Baggot Street Lower, D02 Y754 Dublin 2, Ireland	EU/1/12/787	11.6.2020
20.5.2020	Tybost	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/872	25.5.2020

— **Modification 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
20.5.2020	Emgality	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1330	27.5.2020

— **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
18.5.2020	Lydaxx	tulathromycin	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/253	Solution for injection	QJ01FA94	19.5.2020

— **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
4.5.2020	Apoquel	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	7.5.2020
4.5.2020	Loxicom	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate, Monaghan, Ireland	EU/2/08/090	7.5.2020
12.5.2020	Equilis Prequenza Te	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/057	15.5.2020
18.5.2020	Equilis Prequenza	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/056	20.5.2020
18.5.2020	Equilis Te	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/055	20.5.2020
27.5.2020	CYTOPOINT	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/205	27.5.2020
27.5.2020	Porcilis PCV ID	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/15/187	2.6.2020

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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