

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 November 2021 to 30 November 2021***(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 527/01)

⁽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
12.11.2021	Libmyris	adalimumab	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/21/1590	Solution for injection	L04AB04	16.11.2021
12.11.2021	Rivaroxaban Mylan	rivaroxaban	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1588	Tablet	B01AF01	3.12.2021
15.11.2021	Hukyndra	adalimumab	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/21/1589	Solution for injection	L04AB04	16.11.2021
15.11.2021	Sugammadex Mylan	sugammadex	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1583	Solution for injection	V03AB35	3.12.2021
15.11.2021	Vumerity	diroximel fumarate	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/21/1585	Gastro-resistant capsule, hard	L04AX09	16.11.2021
18.11.2021	GAVRETO	pralsetinib	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	Capsule, hard	L01EX23	22.11.2021
18.11.2021	QINLOCK	ripretinib	Deciphera Pharmaceuticals (Netherlands) B.V. Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland	EU/1/21/1569	Tablet	L01EX19	24.11.2021
22.11.2021	Artesunate Amivas	artesianate	Amivas Ireland Limited Durands Court 7, Parnell Street, Waterford, Ireland	EU/1/21/1582	Powder and solvent for solution for injection	P01BE03	24.11.2021
22.11.2021	Brukinsa	zanubrutinib	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/21/1576	Capsule, hard	L01EL03	23.11.2021
22.11.2021	Trodelvy	sacituzumab govitecan	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/21/1592	Powder for concentrate for solution for infusion	L01FX17	23.11.2021

— **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
15.11.2021	Raylumis	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	—	17.11.2021

— **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
3.11.2021	Besponsa	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/17/1200	4.11.2021
3.11.2021	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	3.11.2021
3.11.2021	Extavia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/454	8.11.2021
3.11.2021	Fulvestrant Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1253	4.11.2021
3.11.2021	Lamzede	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/17/1258	5.11.2021
3.11.2021	Pregabalin Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/997	4.11.2021
3.11.2021	Pregabalin Mylan Pharma	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/15/998	5.11.2021
3.11.2021	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	4.11.2021
9.11.2021	Clopidogrel Viartis	Viartis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	30.11.2021
9.11.2021	Enyglid	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/580	1.12.2021
9.11.2021	Luxturna	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1331	10.11.2021
9.11.2021	Sutent	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/06/347	10.11.2021

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
9.11.2021	Talmanco	Viartis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/16/1153	1.12.2021
9.11.2021	Tegsedi	Akcea Therapeutics Ireland Ltd Regus House, Harcourt Centre, Harcourt Road, Dublin 2, Ireland	EU/1/18/1296	30.11.2021
9.11.2021	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	10.11.2021
11.11.2021	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	12.11.2021
12.11.2021	Akynzeo	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	19.11.2021
12.11.2021	Atriance	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/403	15.11.2021
12.11.2021	Atripla	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/07/430	15.11.2021
12.11.2021	Daptomycin Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/17/1175	16.11.2021
12.11.2021	Dzuvéo	Laboratoire Aguettant 1 Rue Alexander Fleming, 69007 Lyon, France	EU/1/18/1284	16.11.2021
12.11.2021	Edistride	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1052	15.11.2021
12.11.2021	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	2.12.2021
12.11.2021	Evoltra	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/334	16.11.2021
12.11.2021	Iasibon	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/10/659	16.11.2021
12.11.2021	Jyseleca	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1480	15.11.2021
12.11.2021	Lacosamide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/17/1230	15.11.2021
12.11.2021	Lyrca	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	3.12.2021
12.11.2021	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallengbæk Strand, Danmark	EU/1/16/1094	1.12.2021

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
12.11.2021	Nucala	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/15/1043	15.11.2021
12.11.2021	Olanzapine Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/08/475	15.11.2021
12.11.2021	Olumiant	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	16.11.2021
12.11.2021	Sevelamer carbonate Winthrop	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/14/952	7.12.2021
12.11.2021	SomaKit TOC	Advanced Accelerator Applications 20 rue Diesel, 01630 Saint-Genis-Pouilly, France	EU/1/16/1141	16.11.2021
12.11.2021	Steglujan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1266	15.11.2021
12.11.2021	Stelara	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/08/494	15.11.2021
12.11.2021	Suliqua	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/16/1157	15.11.2021
12.11.2021	Tadalafil Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/17/1177	15.11.2021
12.11.2021	Tivicay	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/13/892	17.11.2021
12.11.2021	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	3.12.2021
12.11.2021	Xermelo	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/17/1224	8.12.2021
15.11.2021	Aldurazyme	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/03/253	7.12.2021
15.11.2021	Brilique	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/655	17.11.2021
15.11.2021	Clopidogrel Taw Pharma	Taw Pharma (Ireland) Limited 104 Lower Baggot Street, Dublin 2, Ireland	EU/1/09/559	25.11.2021

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15.11.2021	Dovato	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/19/1370	17.11.2021
15.11.2021	Emtricitabine/ Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1133	16.11.2021
15.11.2021	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/00/170	16.11.2021
15.11.2021	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	17.11.2021
15.11.2021	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	17.11.2021
15.11.2021	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/11/687	18.11.2021
15.11.2021	Hulio	Viatri Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1319	17.11.2021
15.11.2021	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/884	16.11.2021
15.11.2021	Jorveza	Dr Falk Pharma GmbH Leinenweberstraße 5, 79041 Freiburg im Breis- gau, Deutschland	EU/1/17/1254	16.11.2021
15.11.2021	Kevzara	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/17/1196	16.11.2021
15.11.2021	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	20.11.2021
15.11.2021	Myalepta	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/18/1276	18.11.2021
15.11.2021	Praluent	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/15/1031	16.11.2021
15.11.2021	Remicade	Janssen Biologics B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116	19.11.2021
15.11.2021	Rilutek	Sanofi Mature IP 54 rue La Boétie, 75008, Paris, France	EU/1/96/010	18.11.2021
15.11.2021	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/901	16.11.2021
15.11.2021	Skyrizi	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1361	16.11.2021

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15.11.2021	Thyrogen	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/99/122	17.11.2021
15.11.2021	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	17.11.2021
15.11.2021	Truxima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/16/1167	16.11.2021
15.11.2021	Xeljanz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/17/1178	17.11.2021
15.11.2021	Yellox	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/11/692	2.12.2021
15.11.2021	Zercepac	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1456	16.11.2021
15.11.2021	Zercepac	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1456	16.11.2021
15.11.2021	Zoledronic acid Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/12/786	16.11.2021
15.11.2021	Zonisamide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1093	16.11.2021
18.11.2021	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	21.11.2021
18.11.2021	Aripiprazole Mylan Pharma	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1005	19.11.2021
18.11.2021	Axumin	Blue Earth Diagnostics Ireland Ltd 6th Floor, 2 Grand Canal Square, Dublin 2, Ireland	EU/1/17/1186	23.11.2021
18.11.2021	Aybintio	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1454	22.11.2021
18.11.2021	Beovu	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/19/1417	26.11.2021

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
18.11.2021	Champix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/06/360	19.11.2021
18.11.2021	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutsch- land	EU/1/20/1528	18.11.2021
18.11.2021	Marixino	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/820	22.11.2021
18.11.2021	Ogivri	Viartis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1341	22.11.2021
18.11.2021	Opatanol	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/02/217	19.11.2021
18.11.2021	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	22.11.2021
18.11.2021	Prometax	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/092	19.11.2021
18.11.2021	Ritonavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1242	19.11.2021
18.11.2021	Steglujan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1266	20.11.2021
18.11.2021	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	19.11.2021
18.11.2021	Xagrid	Shire Pharmaceuticals Ireland Limited Block 2 & 3 Miesian Plaza, 50-58 Baggot Street Lower, D02 Y754 Dublin 2, Ireland	EU/1/04/295	19.11.2021
18.11.2021	Xoterna Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/863	19.11.2021
18.11.2021	Zeffix	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/99/114	19.11.2021
18.11.2021	Zeposia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1442	21.11.2021
19.11.2021	Aripiprazole Mylan Pharma	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1005	22.11.2021

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22.11.2021	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	1.12.2021
22.11.2021	BYANLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1453	23.11.2021
22.11.2021	Foclivia	Seqirus S.r.l., Via del Pozzo 3/A, S. Martino, 53035 Monteriggioni (SI), Italia	EU/1/09/577	23.11.2021
22.11.2021	Lacosamide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/17/1230	23.11.2021
22.11.2021	Pregabalin Zentiva k.s	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1166	23.11.2021
22.11.2021	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsværd, Danmark	EU/1/15/992	23.11.2021
22.11.2021	Suliqua	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/16/1157	23.11.2021
22.11.2021	Talmanco	Viatriis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/16/1153	23.11.2021
22.11.2021	TOBI Podhaler	Mylan IRE Healthcare Ltd Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/10/652	23.11.2021
22.11.2021	Zypadhera	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/479	23.11.2021
23.11.2021	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	23.11.2021
26.11.2021	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	30.11.2021
26.11.2021	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	26.11.2021
26.11.2021	Corbilta	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/13/859	30.11.2021
26.11.2021	Kispalyx	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/16/1128	29.11.2021
26.11.2021	Lenvima	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/15/1002	29.11.2021

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26.11.2021	Lyxumia	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/12/811	29.11.2021
26.11.2021	NeoRecormon	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/97/031	1.12.2021
26.11.2021	Pritor	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/089	30.11.2021
26.11.2021	Relvar Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/13/886	29.11.2021
26.11.2021	Repatha	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1016	29.11.2021
26.11.2021	Replagal	Shire Human Genetic Therapies AB Lindhagensgatan 120, 112 51, Stockholm, Sverige	EU/1/01/189	6.12.2021
26.11.2021	Rivaroxaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1488	24.10.2021
26.11.2021	Rivaroxaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1488	30.11.2021
26.11.2021	Upravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	29.12.2021
29.11.2021	Carmustine Obvius	Obvius Investment B.V. De Cuserstraat 93, 1081 CN Amsterdam, Nederland	EU/1/18/1278	1.12.2021
29.11.2021	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	30.11.2021
29.11.2021	IntronA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/99/127	1.12.2021
29.11.2021	Simulect	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/084	30.11.2021

— **Withdrawal of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

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3.11.2021	Pregabalin Mylan Pharma	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/15/998	5.11.2021
15.11.2021	Atripla	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/07/430	16.11.2021
18.11.2021	Skysona	bluebird bio (Netherlands) B.V. Stadsplateau 7, WTC Utrecht, 3521 AZ Utrecht, Nederland	EU/1/21/1563	19.11.2021
30.11.2021	IntronA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/99/127	1.12.2021

— **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
11.11.2021	Felpreva	tigolaner/emo-depside/prazi-quantel	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/21/277	Spot-on solution	QP52AA51	12.11.2021

— **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
3.11.2021	Chanhold	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/19/236	5.11.2021
3.11.2021	Equilis Prequenza	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/056	5.11.2021
3.11.2021	Equilis Prequenza Te	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/057	5.11.2021
3.11.2021	Kexxtone	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/12/145	4.11.2021
11.11.2021	Cepedex	CP Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/16/200	25.11.2021
11.11.2021	Coliprotec F4/F18	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/16/202	15.11.2021
12.11.2021	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	16.11.2021
12.11.2021	Simparica Trio	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/243	16.11.2021
26.11.2021	PREVEXXION RN	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/254	3.12.2021
29.11.2021	NexGard Combo	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/267	30.11.2021

— **Withdrawal of a marketing authorisation** (Article 38 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
15.11.2021	Coliprotec F4	Prevtec Microbia GmbH Geyerspergerstr 27, 80689 München, Deutsch- land	EU/2/14/180	7.12.2021

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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