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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2024 to 31 May 2024

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]) or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council ([2]))

(C/2024/3877)

— **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
16.5.2024	Jubbonti	denosumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1813	Solution for injection	M05BX04	21.5.2024
16.5.2024	Omlyclo	Omalizumab	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1817	Solution for injection in a pre-filled syringe	R03DX05	24.5.2024
17.5.2024	Awiqli	insulin icodec	Novo Nordisk A/S Novo Alle 1, 2880 Bagsvaerd, Danmark	EU/1/24/1815	Solution for injection in pre-filled pen	A10AE07	21.5.2024
17.5.2024	FABHALTA	iptacopan	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/24/1802	Capsule, hard	L04AJ08	21.5.2024
17.5.2024	Wyost	denosumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1812	Solution for injection	M05BX04	21.5.2024
27.5.2024	Lytenava	bevacizumab gamma	Outlook Therapeutics Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/24/1798	Solution for injection	S01LA08	28.5.2024

([1]) OJ L 136, 30.4.2004, p. 1.
([2]) OJ L 4, 7.1.2019, p. 43.

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
27.5.2024	Neoatricon	dopamine hydrochloride	BrePco Biopharma Ltd. Suite One, The Avenue, Beacon Court, Sandyford, Dublin D18HX31, Ireland	EU/1/24/1804	Solution for infusion	C01CA04	28.5.2024
29.5.2024	Agilus	Dantrolene sodium hemiheptahydrate	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/24/1805	Powder for solution for injection	M03CA01	30.5.2024
29.5.2024	Qalsody	tofersen	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/23/1783	Solution for injection	N07XX22	3.6.2024

— **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
6.5.2024	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	7.5.2024
6.5.2024	Circadin	RAD Neurim Pharmaceuticals EEC SARL 4 rue de Marivaux, 75002 Paris, France	EU/1/07/392	7.5.2024
6.5.2024	Eliquis	Bristol-Myers Squibb/Pfizer EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/11/691	8.5.2024
6.5.2024	Epclusa	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/16/1116	7.5.2024
6.5.2024	Fendrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/04/299	8.5.2024
6.5.2024	Kanuma	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1033	7.5.2024
6.5.2024	Kisplyx	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/16/1128	7.5.2024
6.5.2024	Orphacol	THERAVIA 16 Rue Montrosier, 92200 Neuilly-sur-Seine, France	EU/1/13/870	14.5.2024
6.5.2024	VEGZELMA	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/22/1667	7.5.2024
6.5.2024	Xenical	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/98/071	8.5.2024
10.5.2024	Armisarte	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/15/1063	13.5.2024
10.5.2024	Darunavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	13.5.2024

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
10.5.2024	Fingolimod Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1450	13.5.2024
10.5.2024	Lojuxta	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/13/851	15.5.2024
10.5.2024	Nilemdo	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1425	13.5.2024
10.5.2024	Nustendi	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1424	14.5.2024
10.5.2024	PreHevbri	VBI Vaccines B.V. Delflandlaan 1, Queen's Tower Office Number 714, 1062 EA Amsterdam, Nederland	EU/1/22/1641	15.5.2024
10.5.2024	QUVIVIQ	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/22/1638	14.5.2024
10.5.2024	Revolade	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/612	13.5.2024
10.5.2024	Thalidomide Lipomed	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/22/1676	13.5.2024
10.5.2024	Thyrogen	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/99/122	14.5.2024
10.5.2024	Trevicta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/971	14.5.2024
10.5.2024	Tyverb	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/440	14.5.2024
15.5.2024	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	16.5.2024

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
16.5.2024	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	17.5.2024
16.5.2024	Bondronat	Atnahs Pharma Netherlands B.V. Copenhagen Towers, Ørestads Boulevard 108, 5.tv, DK-2300 København S, Danmark	EU/1/96/012	17.5.2024
16.5.2024	Cufence	Univar Solutions B.V. Schouwburgplein 30, Rotterdam, 3012 CL, Nederland	EU/1/19/1365	21.5.2024
16.5.2024	Giapreza	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/19/1384	17.5.2024
16.5.2024	IBRANCE	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/16/1147	17.5.2024
16.5.2024	Imvanex	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/13/855	30.5.2024
16.5.2024	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	17.5.2024
16.5.2024	NUBEQA	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/20/1432	17.5.2024
16.5.2024	PecFent	Grünenthal GmbH Zieglerstraße 6, 52078, Aachen, Deutschland	EU/1/10/644	22.5.2024
16.5.2024	Rinvoq	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	17.5.2024
16.5.2024	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	17.5.2024
16.5.2024	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	17.5.2024
16.5.2024	Saphnelo	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1623	17.5.2024
16.5.2024	Vipidia	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/13/844	21.5.2024

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
16.5.2024	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	20.5.2024
17.5.2024	Grasustek	Juta Pharma GmbH Gutenbergstr. 13, 24941, Flensburg, Deutschland	EU/1/19/1375	23.5.2024
17.5.2024	Levetiracetam Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/713	21.5.2024
17.5.2024	Methylthioninium chloride Proveblue	Provepharm S.A.S. 22 rue Marc Donadille, 13013 Marseille, France	EU/1/11/682	22.5.2024
17.5.2024	NUCEIVA	Evolus Pharma B.V. Apollolaan 151, 1077 AR Amsterdam, Nederland	EU/1/19/1364	21.5.2024
17.5.2024	Oxbryta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1622	21.5.2024
17.5.2024	Qdenga	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/22/1699	21.5.2024
17.5.2024	TRISENOX	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/02/204	22.5.2024
21.5.2024	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	22.5.2024
22.5.2024	BEKEMV	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/23/1727	24.5.2024
22.5.2024	BiResp Spiromax	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/921	28.5.2024
22.5.2024	Bosulif	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/818	23.5.2024
22.5.2024	Buccolam	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/11/709	24.5.2024

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
22.5.2024	DuoResp Spiromax	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/920	28.5.2024
22.5.2024	Ebilfumin	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/14/915	23.5.2024
22.5.2024	Eptifibatide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1065	23.5.2024
22.5.2024	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1025	23.5.2024
22.5.2024	Karvezide	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/085	24.5.2024
22.5.2024	Komboglyze	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/11/731	24.5.2024
22.5.2024	Lytgobi	Taiho Pharma Netherlands B.V. Barbara Strozzilaan 201, 1083 HN Amsterdam, Noord-Holland, Nederland	EU/1/23/1741	29.5.2024
22.5.2024	Menveo	GSK Vaccines S.r.l. Via Fiorentina 1, 53100 Siena, Italia	EU/1/10/614	27.5.2024
22.5.2024	Opzelura	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/23/1726	23.5.2024
22.5.2024	Procysbi	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/13/861	29.5.2024
22.5.2024	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/08/444	3.6.2024
22.5.2024	Sialanar	Proveca Pharma Limited 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland	EU/1/16/1135	23.5.2024
23.5.2024	Evrenzo	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1574	23.5.2024

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
23.5.2024	Levetiracetam ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/11/702	28.5.2024
23.5.2024	Levetiracetam Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/701	23.5.2024
23.5.2024	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	23.5.2024
27.5.2024	Aimovig	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/18/1293	28.5.2024
27.5.2024	Camcevi	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1647	28.5.2024
27.5.2024	Columvi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/23/1742	28.5.2024
27.5.2024	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	28.5.2024
27.5.2024	IMJUDO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1713	28.5.2024
27.5.2024	Reyataz	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/03/267	28.5.2024
27.5.2024	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	28.5.2024
29.5.2024	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	26.4.2024
29.5.2024	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	30.5.2024
29.5.2024	Cerdelga	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/14/974	31.5.2024

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
29.5.2024	Desloratadine Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/11/745	1.6.2024
29.5.2024	Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/17/1210	30.5.2024
29.5.2024	Emtricitabine/ Tenofovir disoproxil Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/16/1151	30.5.2024
29.5.2024	Emtricitabine /Tenofovir disoproxil Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1182	6.6.2024
29.5.2024	Myocet liposomal	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Deutschland	EU/1/00/141	3.6.2024
29.5.2024	Omidria	Rayner Surgical (Ireland) Limited The Mill Enterprise Hub, Newtown Link Road, Drogheda, A92 CD3D, Co. Louth, Ireland	EU/1/15/1018	4.6.2024
29.5.2024	Pregabalin Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1011	6.6.2024

— **Issuing of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 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
6.5.2024	Nobilis Multriva RT +IBm+ND+Gm +REOm+EDS	Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/309	Emulsion for injection	QI01AA24	8.5.2024
6.5.2024	Trilocur	trilostane	Emdoka John Lijsenstraat 16, 2321 Hoogstraten, België	EU/2/24/312	Oral suspension	QH02CA01	7.5.2024
6.5.2024	Trilorale	trilostane	Axience Tour Essor, 14 Rue Scandicci, 93500 Pantin, France	EU/2/24/313	Oral suspension	QH02CA01	7.5.2024
10.5.2024	DIVENCE Tetra	Bovine viral diarrhoea virus type 1 and type 2 (subunit, recombinant), bovine parainfluenza 3 virus (inactivated) and bovine respiratory syncytial virus (live) vaccine	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/310	Lyophilisate and solvent for solution for injection	Pending	13.5.2024

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
22.5.2024	Innovax-ND-H5	Newcastle disease, avian influenza and Marek's disease vaccine (live recombinant)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/315	Concentrate and solvent for suspension for injection	QI01AD	23.5.2024
30.5.2024	RESPIVAC TRT	Turkey rhinotracheitis virus, live	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/24/314	Lyophilisate for suspension	QI01AD01	3.6.2024

— **Modification of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 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
6.5.2024	Purevax RCP FeLV	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/048	8.5.2024
6.5.2024	RESPIPORC FLU-pan H1N1	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/209	13.5.2024
6.5.2024	Suiseng Diff/A	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	7.5.2024
6.5.2024	Zulvac BTV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/207	8.5.2024
10.5.2024	ProZinc	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/13/152	14.5.2024
30.5.2024	Advocate	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/03/039	3.6.2024
30.5.2024	Convenia	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/06/059	3.6.2024
30.5.2024	Cortavance	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/06/069	31.5.2024
30.5.2024	MS-H vaccine	Pharmsure Veterinary Products Europe Limited 4 Fitzwilliam Terrace, Strand Road, Bray, WICKLOW A98 T6H6, Ireland	EU/2/11/126	31.5.2024
30.5.2024	NEOLEISH	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/22/290	3.6.2024
30.5.2024	NexGard	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/13/159	31.5.2024
30.5.2024	Syvazul BTV	Laboratorios Syva S.A C/Marqués de la Ensenada16, 28004 Madrid, España	EU/2/18/231	3.6.2024
30.5.2024	UpCard	Vétoquinol SA Magny-Vernois, 70200 Lure, France	EU/2/15/184	4.6.2024

— **Suspension of a marketing authorisation** (Article 45 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 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
15.5.2024	Kexxtone	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/12/145	17.5.2024

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