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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2023 to 31 December 2023

(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/2024/910)

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

— **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
1.12.2023	Zilbrysq	zilucoplan	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/23/1764	Solution for injection	L04A	4.12.2023
7.12.2023	ELREXFIO	elranatamab	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1770	Solution for injection	Pending	8.12.2023
7.12.2023	Elucirem	gadopiclenol	Guerbet 15 rue des Vanesses, 93420, Villepinte, France	EU/1/23/1772	Solution for injection	V08CA	8.12.2023
7.12.2023	JEMPERLI	dostarlimab	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	Concentrate for solution for infusion	L01FF07	11.12.2023
7.12.2023	Veoza	fezolinetant	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/23/1771	Film-coated tablet	G02CX06	12.12.2023
7.12.2023	Vueway	gadopiclenol	Bracco Imaging SPA Via Egidio Folli, 50 20134 Milano, Italia	EU/1/23/1773	Solution for injection	V08CA12	8.12.2023
13.12.2023	Dimethyl Fumarate Accord	dimethyl fumarate	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1711	Gastro-resistant capsule, hard	L04AX07	13.12.2023
13.12.2023	Dimethyl fumarate Mylan	dimethyl fumarate	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/22/1634	Gastro-resistant capsule, hard	L04AX07	13.12.2023
13.12.2023	Dimethyl fumarate Neuraxpharm	dimethyl fumarate	Laboratorios Lesvi, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí — Barcelona, España	EU/1/22/1637	Gastro-resistant capsule, hard	L04AX07	16.12.2023
13.12.2023	Dimethyl fumarate Polpharma	dimethyl fumarate	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/22/1635	Gastro-resistant capsule, hard	L04AX07	13.12.2023

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
13.12.2023	Dimethyl Fumarate Teva	dimethyl fumarate	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/22/1702	Gastro-resistant capsule, hard	L04AX07	15.12.2023
14.12.2023	AGAMREE	vamorolone	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Straße 8, 79539 Lörrach, Deutschland	EU/1/23/1776	Oral suspension		15.12.2023
15.12.2023	Loargys	pegzilarginase	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/23/1774	Solution for injection or infusion	A16AB24	18.12.2023
22.12.2023	Rezzayo	Rezafungin	Mundipharma GmbH De-Saint-Exupery-Strasse 10, 60549 Frankfurt Am Main, Deutschland	EU/1/23/1775	Powder for concentrate for solution for infusion	J02AX08	22.12.2023

— **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
1.12.2023	Bemfola	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/13/909	5.12.2023
1.12.2023	Beyfortus	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/22/1689	4.12.2023
1.12.2023	Clopidogrel Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	5.12.2023
1.12.2023	Dificlir	Tillotts Pharma GmbH Warmbacher Strasse 80, 79618 Rheinfelden, Deutschland	EU/1/11/733	4.12.2023
1.12.2023	Vaxelis	MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, Nederland	EU/1/15/1079	4.12.2023
1.12.2023	Vizamyl	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/14/941	6.12.2023
1.12.2023	VPRIV	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/10/646	6.12.2023
7.12.2023	Ammonaps	Immedica Pharma AB Solnavagen 3 H, Stockholm, 113 63, Sverige	EU/1/99/120	8.12.2023
7.12.2023	Atazanavir Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/19/1353	14.12.2023
7.12.2023	Benepali	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/15/1074	12.12.2023
7.12.2023	Besremi	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/18/1352	11.12.2023
7.12.2023	Byooviz	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/21/1572	12.12.2023
7.12.2023	CARVYKTI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	11.12.2023
7.12.2023	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	11.12.2023
7.12.2023	Fasturtec	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/00/170	8.12.2023
7.12.2023	Febuxostat Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1347	14.12.2023
7.12.2023	Fluad Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/20/1433	13.12.2023
7.12.2023	Flucelvax Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/18/1326	14.12.2023

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
7.12.2023	Hemgenix	CSL Behring GmbH D-35041 Marburg, Deutschland	EU/1/22/1715	15.12.2023
7.12.2023	Imatinib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/13/845	11.12.2023
7.12.2023	Intrarosa	Endoceutics S.A. Rue Belliard 40, 1040 Bruxelles, Belgique/ Belliardstraat 40, 1040 Brussel, België	EU/1/17/1255	8.12.2023
7.12.2023	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	11.12.2023
7.12.2023	Lyrica	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	12.12.2023
7.12.2023	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/331	8.12.2023
7.12.2023	Omnitrope	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/06/332	11.12.2023
7.12.2023	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	11.12.2023
7.12.2023	Pregabalin Pfizer	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/14/916	12.12.2023
7.12.2023	Steglatro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1267	8.12.2023
7.12.2023	Striascan	CIS bio international RN 306 — Saclay, B.P. 32, F-91192 Gif-sur-Yvette Cedex, France	EU/1/19/1372	8.12.2023
7.12.2023	Sycrest	Organon N.V. Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640	10.12.2023
7.12.2023	Symkevi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/18/1306	8.12.2023
7.12.2023	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	12.12.2023
7.12.2023	Tecovirimat SIGA	SIGA Technologies Netherlands B.V. Prinsenhil 29, Breda 4825 AX, Nederland	EU/1/21/1600	8.12.2023
7.12.2023	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	11.12.2023
7.12.2023	TOOKAD	Steba Biotech B.A. 14a Rue des Bains, L-1212, Luxembourg, Luxembourg	EU/1/17/1228	11.12.2023
7.12.2023	Vizimpro	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1354	8.12.2023

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
7.12.2023	Vyepti	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/21/1599	11.12.2023
7.12.2023	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	11.12.2023
11.12.2023	AYVAKYT	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/20/1473	12.12.2023
11.12.2023	Brineura	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, Ireland	EU/1/17/1192	12.12.2023
11.12.2023	Erelzi	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1195	15.12.2023
11.12.2023	Evkeeza	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/21/1551	12.12.2023
11.12.2023	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	12.12.2023
11.12.2023	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	13.12.2023
11.12.2023	Moventig	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/14/962	12.12.2023
11.12.2023	Nepexto	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1436	13.12.2023
11.12.2023	Pedea	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/04/284	12.12.2023
11.12.2023	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	12.12.2023
11.12.2023	Ventavis	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/255	12.12.2023
14.12.2023	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	18.12.2023
14.12.2023	Enbrel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/126	19.12.2023
14.12.2023	NexoBrid	MediWound Germany GmbH Hans-Sachs-Strasse 100, 65428 Rüsselsheim, Deutschland	EU/1/12/803	21.12.2023
14.12.2023	Pepaxti	Oncopeptides AB (publ) Västra Trädgårdsgatan 15, 111 53 Stockholm, Sverige	EU/1/22/1669	15.12.2023

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
18.12.2023	Clopidogrel Taw Pharma	Taw Pharma (Ireland) Limited 104 Lower Baggot Street, Dublin 2, Ireland	EU/1/09/559	19.12.2023
18.12.2023	Clopidogrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	21.12.2023
19.12.2023	Amvuttra	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/22/1681	20.12.2023
19.12.2023	Ibandronic Acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/642	21.12.2023
19.12.2023	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/12/782	20.12.2023
19.12.2023	Rinvoq	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	20.12.2023
19.12.2023	Tacforius	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/17/1244	8.1.2024
19.12.2023	Tevimbra	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/23/1758	22.12.2023

— **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
11.12.2023	Onbevzi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1499	13.12.2023

— **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
11.12.2023	Advocate	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/03/039	12.12.2023
18.12.2023	Baycox Iron	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/239	20.12.2023
19.12.2023	Credelio Plus	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/21/271	21.12.2023
19.12.2023	ERAVAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/16/199	20.12.2023

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
19.12.2023	ERYSENG	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/14/166	21.12.2023
19.12.2023	Evalon	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/16/194	20.12.2023
19.12.2023	EVANT	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/18/233	21.12.2023
19.12.2023	Hiprabovis IBR Marker Live	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/10/114	21.12.2023
19.12.2023	Leucogen	Virbac 1ère Avenue — 2065 m — L.I.D., 06516 Carros CEDEX, France	EU/2/09/096	20.12.2023
19.12.2023	Meloxoral	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/10/111	20.12.2023
19.12.2023	MHYOSPHERE PCV ID	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/20/259	20.12.2023
19.12.2023	Nobivac LeuFel	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/17/217	20.12.2023
19.12.2023	Nobivac Myx-o-RHD PLUS	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/19/244	21.12.2023
19.12.2023	RHINISENG	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/10/109	22.12.2023
19.12.2023	STARTVAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/08/092	22.12.2023
19.12.2023	Suvaxyn Circo	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/223	21.12.2023
19.12.2023	Suvaxyn Circo + MH RTU	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/15/190	21.12.2023
19.12.2023	UBAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/18/227	21.12.2023

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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