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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 March 2024 to 31 March 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/2024/2791)

— **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
19.03.2024	Abecma	idecabtagene vicleucel	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	Dispersion for infusion	L01	22.03.2024
21.03.2024	EXBLIFEP	cefepime / enmetazobactam	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Co. Dublin, Ireland	EU/1/24/1794	Powder for concentrate for solution for infusion	J01DE51	23.03.2024
21.03.2024	Niapelf	Paliperidone	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1795	Prolonged-release suspension for injection	N05AX13	02.04.2024
21.03.2024	Ryzneuta	efbemalenograstim alfa	Evive Biotechnology Ireland LTD Second Floor, Joshua Dawson House, Dawson Street, Dublin, D02 RY95, Ireland	EU/1/24/1793	Solution for injection	L03AA18	22.03.2024

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

— **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
01.03.2024	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, 1831 Diegem, België	EU/1/08/473	06.03.2024
01.03.2024	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, D02 R296, Ireland	EU/1/18/1290	04.03.2024
01.03.2024	Pepaxti	Oncopeptides AB (publ) Luntmakargatan 46, 111 37 Stockholm, Sverige	EU/1/22/1669	04.03.2024
01.03.2024	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	04.03.2024
01.03.2024	Zoledronic acid Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/759	04.03.2024
11.03.2024	CARVYKTI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	13.03.2024
11.03.2024	Ecansya	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/12/763	12.03.2024
11.03.2024	Ondexxya	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1345	12.03.2024
11.03.2024	Prevenar 20	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1612	12.03.2024
11.03.2024	Striascan	CIS bio international RN 306 – Saclay, B.P. 32, F-91192 Gif-sur-Yvette Cedex, France	EU/1/19/1372	12.03.2024
11.03.2024	Upstaza	PTC Therapeutics International Limited 70 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/22/1653	12.03.2024
11.03.2024	Waylivra	Akcea Therapeutics Ireland Ltd St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland	EU/1/19/1360	12.03.2024

14.03.2024	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419	15.03.2024
14.03.2024	Epysqli	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/23/1735	19.03.2024
14.03.2024	Firazyr	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/08/461	15.03.2024
14.03.2024	Inbrija	Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/19/1390	21.03.2024
14.03.2024	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/00/152	04.04.2024
14.03.2024	JEVTANA	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/11/676	15.03.2024
14.03.2024	Mozobil	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/09/537	15.03.2024
14.03.2024	Tarceva	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/05/311	15.03.2024
14.03.2024	Yargesa	Piramal Critical Care B.V. Rouboslaan 32 (ground floor), 2252 TR, Voorschoten, Nederland	EU/1/17/1176	19.03.2024
14.03.2024	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	15.03.2024
18.03.2024	Mekinist	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/931	20.03.2024
19.03.2024	Braftovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1314	21.03.2024

19.03.2024	Fintepla	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/20/1491	21.03.2024
19.03.2024	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	20.03.2024
19.03.2024	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	20.03.2024
19.03.2024	Qarziba	Recordati Netherlands B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1191	22.03.2024
19.03.2024	Xromi	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, D01 W2T2, Ireland	EU/1/19/1366	20.03.2024
21.03.2024	Aldurazyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/03/253	22.03.2024
21.03.2024	Ambrisentan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1368	25.03.2024
21.03.2024	BIMERVAX	Hipra Human Health, S.L.U. Avda. la Selva, 135, 17170 Amer (Girona), España	EU/1/22/1709	22.03.2024
21.03.2024	Celdoxome pegylated liposomal	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/22/1666	02.04.2024
21.03.2024	Cibinqo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	22.03.2024
21.03.2024	Clopidogrel ratiopharm	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/14/975	26.03.2024
21.03.2024	Dovato	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/19/1370	22.03.2024
21.03.2024	Enjaymo	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/22/1687	27.03.2024

21.03.2024	Giapreza	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/19/1384	22.03.2024
21.03.2024	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	22.03.2024
21.03.2024	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	22.03.2024
21.03.2024	Nemdatine	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/13/824	22.03.2024
21.03.2024	Nexviadyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1579	27.03.2024
21.03.2024	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	22.03.2024
21.03.2024	Spikevax	MODERNA BIOTECH SPAIN, S.L.	EU/1/20/1507	25.03.2024
21.03.2024	Tepadina	ADIENNE S.r.l.S.U. Via Galileo Galilei 19, 20867 Caponago (MB), Italia	EU/1/10/622	25.03.2024
21.03.2024	Uplizna	Horizon Therapeutics Ireland DAC 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland	EU/1/21/1602	22.03.2024
21.03.2024	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	22.03.2024
25.03.2024	ABILIFY MAINTENA	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/13/882	05.04.2024
25.03.2024	Aerinaze	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/07/399	26.03.2024
25.03.2024	CellCept	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/96/005	26.03.2024

25.03.2024	GAVRETO	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	26.03.2024
25.03.2024	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	02.04.2024
25.03.2024	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	26.03.2024
25.03.2024	Myfenax	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/438	26.03.2024
25.03.2024	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	26.03.2024
25.03.2024	PecFent	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/10/644	27.03.2024
25.03.2024	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	26.03.2024
25.03.2024	Sutent	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/347	26.03.2024
25.03.2024	Zolgensma	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1443	27.03.2024
26.03.2024	Glivec	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/198	02.04.2024
27.03.2024	Anagrelide Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/17/1256	02.04.2024
27.03.2024	Brilique	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/655	02.04.2024
27.03.2024	Cetrotide	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/99/100	03.04.2024

27.03.2024	Effentora	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/441	03.04.2024
27.03.2024	Febuxostat Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1347	04.04.2024
27.03.2024	Instanyl	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/09/531	03.04.2024
27.03.2024	Myclausen	Passauer Pharma GmbH Eiderstedter Weg 3, 14129 Berlin, Deutschland	EU/1/10/647	04.04.2024
27.03.2024	Nexium Control	GlaxoSmithKline Dungarvan Limited Dungarvan, Co. Waterford, Ireland	EU/1/13/860	02.04.2024
27.03.2024	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	02.04.2024
27.03.2024	Prasugrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1273	02.04.2024
27.03.2024	Puregon	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/96/008	02.04.2024
27.03.2024	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	02.04.2024
27.03.2024	Repatha	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1016	02.04.2024
27.03.2024	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	03.04.2024
27.03.2024	Segluromet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1265	02.04.2024
27.03.2024	Sixmo	L. Molteni & C. dei F.lli Alitti Società di .Esercizio .S.p.A Strada Statale 67, Loc. Granatieri, 50018 Scandicci (Firenze), Italia	EU/1/19/1369	02.04.2024

27.03.2024	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	02.04.2024
27.03.2024	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	02.04.2024

— **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
01.03.2024	Zoledronic acid Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/759	04.03.2024
11.03.2024	VidPrevtyn Beta	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/21/1580	12.03.2024
27.03.2024	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	02.04.2024

— **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
11.03.2024	Profender	Vetoquinol S.A. Magny-Vernois, 70200 Lure, France	EU/2/05/054	12.03.2024
21.03.2024	Baycox Iron	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/239	22.03.2024
21.03.2024	ReproCyc Parvo-FLEX	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/19/237	25.03.2024
27.03.2024	AdTab	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	02.04.2024

27.03.2024	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	02.04.2024
27.03.2024	Suprelorin	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/07/072	02.04.2024

— **Withdrawal 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)

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
27.03.2024	Bovilis Blue-8	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/218	02.04.2024
27.03.2024	Enteroporc Coli	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/268	02.04.2024

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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