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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2023 to 30 September 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/2023/298)

[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
15.9.2023	Apretude	cabotegravir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/23/1760	Film-coated tablet Prolonged-release suspension for injection	J05AJ04	20.9.2023
15.9.2023	Enrylaze	crisantaspase	Jazz Pharmaceuticals Ireland Limited 5th Floor, Waterloo Exchange, Waterloo Road, Dublin 4, D04 E5W7, Ireland	EU/1/23/1747	Solution for injection or infusion	L01XX02	21.9.2023
15.9.2023	Inaqovi	decitabine / cedazuridine	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/23/1756	Film-coated tablet	L01BC58	18.9.2023
15.9.2023	Litfulo	ritlecitinib	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1755	Capsule, hard	L04AF08	18.9.2023
15.9.2023	Lyfnua	gefapixant	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1613	Film-coated tablet	R05DB29	20.9.2023
15.9.2023	ORSERDU	elacestrant	Stemline Therapeutics B.V. Basisweg 10, 1043 AP, Amsterdam, Noord-Holland, Nederland	EU/1/23/1757	Film-coated tablet	L02BA04	18.9.2023
15.9.2023	Tevimbra	tislelizumab	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1758	Concentrate for solution for infusion	L01FF09	19.9.2023
15.9.2023	Tyenne	tocilizumab	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/23/1754	Concentrate for solution for infusion Solution for injection	L04AC07	18.9.2023
15.9.2023	Yesafili	aflibercept	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/23/1751	Solution for injection in a vial	S01LA05	19.9.2023
22.9.2023	Tepkinly	epcoritamab	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	Solution for injection	Pending	25.9.2023

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
22.9.2023	Tyruko	natalizumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/23/1745	Concentrate for solution for infusion	L04AA23	25.9.2023
29.9.2023	Degarelix Accord	degarelix acetate	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/23/1753	Powder and solvent for solution for injection	L02BX02	3.10.2023

— **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
1.9.2023	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	4.9.2023
1.9.2023	Adtralza	Leo Pharma A/S Industriparken 55, 2750 Ballerup, Danmark	EU/1/21/1554	7.9.2023
1.9.2023	Emgality	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1330	4.9.2023
1.9.2023	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	4.9.2023
1.9.2023	Poteligeo	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/18/1335	19.9.2023
11.9.2023	Apealea	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/18/1292	12.9.2023
11.9.2023	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	12.9.2023
11.9.2023	Fulphila	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1329	12.9.2023
11.9.2023	GHRYVELIN	Atnahs Pharma Netherlands B.V. Copenhagen Towers, Ørestads Boulevard 108, 5. tv, DK-2300 København S, Danmark	EU/1/18/1337	15.9.2023
11.9.2023	Imlygic	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1064	13.9.2023
11.9.2023	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030	12.9.2023
11.9.2023	Irbesartan Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/06/376	14.9.2023
11.9.2023	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	12.9.2023
11.9.2023	Lumeblue	Alfasigma S.p.A. Via Ragazzi del '99, n.5, 40133 Bologna, Italia	EU/1/20/1470	12.9.2023
11.9.2023	OKEDI	Laboratorios Farmacéuticos Rovi, S.A. Julián Camarillo 35, 28037 Madrid, España	EU/1/21/1621	12.9.2023
11.9.2023	Opatanol	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/02/217	12.9.2023
11.9.2023	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	12.9.2023
11.9.2023	Vimizim	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/14/914	12.9.2023

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
12.9.2023	Fulphila	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/18/1329	14.9.2023
15.9.2023	Afinitor	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/538	18.9.2023
15.9.2023	Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1092	18.9.2023
15.9.2023	Bevespi Aerosphere	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1339	22.9.2023
15.9.2023	Celsentri	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/07/418	21.9.2023
15.9.2023	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	18.9.2023
15.9.2023	Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1222	18.9.2023
15.9.2023	Esperoct	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/19/1374	21.9.2023
15.9.2023	Fortacin	Recordati Ireland Ltd Raheens East, Ringaskiddy Co. Cork P43 KD30, Ireland	EU/1/13/881	21.9.2023
15.9.2023	GAVRETO	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	18.9.2023
15.9.2023	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	18.9.2023
15.9.2023	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/11/687	21.9.2023
15.9.2023	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/945	18.9.2023
15.9.2023	Instanyl	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/09/531	22.9.2023
15.9.2023	Irbesartan / Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	19.9.2023
15.9.2023	Iressa	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/09/526	18.9.2023
15.9.2023	Jinarc	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/15/1000	18.9.2023

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
15.9.2023	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	18.9.2023
15.9.2023	Kinzalkomb	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/02/214	18.9.2023
15.9.2023	Kiovig	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/05/329	21.9.2023
15.9.2023	Levetiracetam Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/889	18.9.2023
15.9.2023	MicardisPlus	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/02/213	21.9.2023
15.9.2023	M-M-RVAXPRO	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/06/337	18.9.2023
15.9.2023	Olumiant	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	18.9.2023
15.9.2023	Orgovyx	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1642	18.9.2023
15.9.2023	Pregabalin Sandoz GmbH	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/15/1012	18.9.2023
15.9.2023	Prolia	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/10/618	18.9.2023
15.9.2023	Remsima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/13/853	18.9.2023
15.9.2023	Sitagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/22/1661	18.9.2023
15.9.2023	Spevigo	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	18.9.2023
15.9.2023	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España	EU/1/20/1507	15.9.2023
15.9.2023	Sugammadex Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1583	19.9.2023
15.9.2023	Tecfidera	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/13/837	19.9.2023
15.9.2023	Tenkasi	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/989	18.9.2023

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
15.9.2023	Tezspire	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1677	18.9.2023
15.9.2023	Toviaz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/386	18.9.2023
15.9.2023	Tygacil	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/336	18.9.2023
15.9.2023	Vantobra	PARI Pharma GmbH Moosstraße 3, 82319 Starnberg, Deutschland	EU/1/18/1350	19.9.2023
15.9.2023	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	18.9.2023
15.9.2023	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	26.9.2023
15.9.2023	Vyvgart	argenx BV Industriepark-Zwijnaarde 7, 9052 Gent, België	EU/1/22/1674	20.9.2023
15.9.2023	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	18.9.2023
15.9.2023	Zytiga	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/11/714	18.9.2023
18.9.2023	Rydapt	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1218	20.9.2023
22.9.2023	Ciambra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/1055	25.9.2023
22.9.2023	Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	25.9.2023
22.9.2023	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	25.9.2023
22.9.2023	Imcivree	Rhythm Pharmaceuticals Netherlands B.V. Radarweg 29, 1043 NX Amsterdam, Nederland	EU/1/21/1564	26.9.2023
22.9.2023	Imvanex	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/13/855	5.10.2023
22.9.2023	Kesimpta	Novartis Ireland Limited Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland	EU/1/21/1532	3.10.2023
22.9.2023	Myozyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/333	28.9.2023
22.9.2023	Ranivisio	Midas Pharma GmbH Rheinstraße 49, D-55218 Ingelheim, Deutschland	EU/1/22/1673	25.9.2023

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
22.9.2023	Sunosi	Atnahs Pharma Netherlands B. V. Copenhagen Towers, Ørestads Boulevard 108, 5. tv, DK-2300 København S, Denmark	EU/1/19/1408	25.9.2023
22.9.2023	TAVLESSE	Instituto Grifols, S.A. Can Guasc, 2, Parets del Vallès, 08150 Barcelona, España	EU/1/19/1405	27.9.2023
22.9.2023	Vaxchora	Bavarian Nordic A/S Philip Heymans Allé 3, DK-2900 Hellerup, Danmark	EU/1/20/1423	25.9.2023
22.9.2023	Vildagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/21/1611	26.9.2023

— **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
11.9.2023	Lenalidomide Krka d.d. Novo mesto	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/20/1520	14.9.2023
11.9.2023	Pandemic influenza vaccine H5N1 BAXTER	Resilience Biomanufacturing Ireland Limited 2 Shelbourne Buildings, Crampton Avenue, Dublin 4, D04 W3V6, Ireland	EU/1/09/571	15.9.2023

— **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
11.9.2023	YURVAC RHD	Rabbit haemorrhagic disease and RHDV2 vaccine (recombinant)	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/23/298	Emulsion for injection	QI08AV	12.9.2023

— **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
11.9.2023	Apoquel	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	12.9.2023
11.9.2023	Prolevare	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/23/295	12.9.2023

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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