Il-Ġurnal Uffiċjali tal-Unjoni Ewropea

C/2026/5455

21.10.2026

MT Is-serje C

Sommarju ta' deċiżjonijiet tal-Unjoni Ewropea dwar l-awtorizzazzjonijiet għat-tqegħid fis-suq tal-prodotti mediċinali minn 1 Settembru 2026 sa 30 Settembru 2026

(Ippubblikat skont l-Artikolu 13 jew l-Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill [1] jew L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill [2])

(C/2026/5455)

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	INN (Denominazzjoni Internazzjonali Komuni)	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Forma farmaċewtika	Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku)	Data ta' notifika
18.9.2026	Evlarco	obicetrapib/ ezetimibe	A. Menarini International Licensing S.A. 12c Impasse Drosbach, 1882 Luxembourg, Luxembourg	EU/1/26/2056	Pillola miksija b'rita	C10BA17	22.9.2026
18.9.2026	ICOTYDE	icotrokinra hydrochloride	Janssen-Cilag International N.V. Turnhoutseweg 30, 2340 Beerse, Antwerp, Belgie	EU/1/26/2063	Pillola miksija b'rita	L04AC28	21.9.2026
18.9.2026	LYROKAUL	Lerodalcibep	LIB Therapeutics B.V. Eurogate III 3e Verdieping, Watermanweg 32, 3067 GG Rotterdam, Nederland	EU/1/26/2061	Soluzzjoni għall-injezzjoni	C10AX19	23.9.2026
18.9.2026	Riociguat Accord	riociguat	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6ª planta, 08039 Barcelona, España	EU/1/26/2059	Pillola miksija b'rita	C02KX05	21.9.2026
18.9.2026	Ruxolitinib Viatris	ruxolitinib	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/26/2064	Pillola	L01EJ01	22.9.2026

[1] ĠU L 136, 30.4.2004, p. 1, ELI: https://data.europa.eu/eli/reg/2004/726/oj.
[2] ĠU L 4, 7.1.2019, p. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

Data tad-dečiżjoni	Isem tal-prodott mediċinali	INN (Denominazzjoni Internazzjonali Komuni)	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Forma farmaċewtika	Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku)	Data ta' notifika
18.9.2026	Susvimo	ranibizumab	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/26/2058	Soluzzjoni għall-injezzjoni	S01LA04	21.9.2026
18.9.2026	Tafamidis Accord	tafamidis	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6ª planta, 08039 Barcelona, España	EU/1/26/2065	Kapsula, ratba	N07XX08	21.9.2026
18.9.2026	Ubeslo	obicetrapib	A. Menarini International Licensing S.A. 12c Impasse Drosbach, 1882 Luxembourg, Luxembourg	EU/1/26/2055	Pillola miksija b'rita	C10AX	22.9.2026
18.9.2026	Zokovea	ensitrelvir	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/26/2062	Pillola	J05AE16	21.9.2026
21.9.2026	Nezglyal	leriglitazone	Minoryx Therapeutics S.L. Av. Ernest Lluch, 32, TCM3, 08302 Mataró, Barcelona, España	EU/1/26/2060	Suspensjoni Orali	A16AX23	22.9.2026
25.9.2026	Aumseqa	aumolertinib	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/25/2006	Pillola miksija b'rita	L01EB11	25.9.2026
25.9.2026	Cavoley	Pegfilgrastim	CuraTeQ Biologics s.r.o Trtinova 260/1, Cakovice, 19600 Prague 9, Česká republika	EU/1/26/2066	Soluzzjoni għall-injezzjoni	L03AA13	29.9.2026

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Miċħud**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
14.9.2026	TACQUELL	Netherlands Cancer Institute Plesmanlaan 121, 1066 CX Amsterdam, Nederland	-	15.9.2026

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
3.9.2026	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	4.9.2026
3.9.2026	JERAYGO	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/24/1818	8.9.2026
3.9.2026	Miglustat Gen.Orph	Gen.Orph 185 Bureaux de la Colline, 92213 Saint Cloud Cedex, France	EU/1/17/1232	4.9.2026
3.9.2026	Symtuza	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/17/1225	4.9.2026
3.9.2026	Zimbus Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1440	4.9.2026
11.9.2026	Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1092	14.9.2026
11.9.2026	BEYONTTRA	Bayer AG 51368 Leverkusen, Deutschland	EU/1/24/1906	14.9.2026
11.9.2026	Brintellix	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/13/891	14.9.2026
11.9.2026	Lixiana	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/15/993	15.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
11.9.2026	Prolia	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/10/618	15.9.2026
11.9.2026	Riluzole Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/12/768	14.9.2026
11.9.2026	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	14.9.2026
11.9.2026	Wezenla	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/24/1823	10.8.2026
11.9.2026	Wezenla	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/24/1823	14.9.2026
11.9.2026	Zokinvy	Integral Pharma Solutions EU Limited 1 Windmill Lane, Dublin 2, Co. Dublin, D02 F206, Ireland	EU/1/22/1660	14.9.2026
11.9.2026	Zolgensma	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1443	18.9.2026
11.9.2026	Zonegran	Amdipharm Limited Unit 17, Northwood House, Northwood Crescent, Northwood, Dublin 9, D09 V504, Ireland	EU/1/04/307	22.9.2026
14.9.2026	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	15.9.2026
14.9.2026	Herwenda	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/23/1762	15.9.2026
14.9.2026	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/945	15.9.2026
14.9.2026	Lazcluze	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1886	15.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
14.9.2026	Miglustat Dipharma	Dipharma Arzneimittel GmbH Offheimer Weg 33, 65549 Limburg a. d. Lahn, Deutschland	EU/1/18/1346	18.9.2026
14.9.2026	Pergoveris	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/07/396	16.9.2026
14.9.2026	Skytrofa	Ascendis Pharma Endocrinology Division A/S Tuborg Boulevard 12, 2900 Hellerup, Danmark	EU/1/21/1607	16.9.2026
14.9.2026	Steqeyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1844	24.8.2026
14.9.2026	Steqeyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1844	17.9.2026
14.9.2026	Sugammadex Adroiq	Extrovis EU Kft. Raktarvarosi Ut 9, Torokbalint, 2045, Magyarország	EU/1/23/1733	16.9.2026
14.9.2026	Tasmar	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/97/044	15.9.2026
14.9.2026	Tepmetko	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/21/1596	16.9.2026
14.9.2026	Xaluprine	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/ Rhein, Deutschland	EU/1/11/727	15.9.2026
14.9.2026	Zyprexa	CHEPLAPHARM Registration GmbH Weiler Straße 5e, 79540 Lörrach, Deutschland	EU/1/96/022	17.9.2026
17.9.2026	Afqlir	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1867	2.10.2026
18.9.2026	Afiveg	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/1965	24.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
18.9.2026	Ahzantive	Formycon AG 82152 Martinsried/Planegg, Deutschland	EU/1/24/1888	21.9.2026
18.9.2026	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	21.9.2026
18.9.2026	Bysumlog	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/26/2030	21.9.2026
18.9.2026	Ebvallo	Pierre Fabre Medicament Les Cauquillous, 81500 Lavaur, France	EU/1/22/1700	22.9.2026
18.9.2026	Eiyzey	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/25/1963	21.9.2026
18.9.2026	Enerzair Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1438	22.9.2026
18.9.2026	Eydenzelt	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/24/1895	29.9.2026
18.9.2026	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	21.9.2026
18.9.2026	Eyluxvi	Biolitec Pharma Limited Zweigniederlassung Jena Otto-Schott-Str. 15, 07745 Jena, Deutschland	EU/1/25/1972	29.9.2026
18.9.2026	FABHALTA	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/24/1802	22.9.2026
18.9.2026	Glyxambi	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/16/1146	22.9.2026
18.9.2026	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	22.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
18.9.2026	Hyftor	Plusultra pharma GmbH Fritz-Vomfelde-Str. 36, 40547 Düsseldorf, Deutschland	EU/1/23/1723	21.9.2026
18.9.2026	Idacio	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/19/1356	23.9.2026
18.9.2026	Jentadueto	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/12/780	22.9.2026
18.9.2026	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/20/1468	21.9.2026
18.9.2026	Litfulo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1755	21.9.2026
18.9.2026	Lunsumio	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1649	21.9.2026
18.9.2026	Mylotarg	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1277	21.9.2026
18.9.2026	MYNZEPLI	Advanz Pharma Limited Unit 17, Northwood House, Northwood Crescent, Dublin 9, D09 V504, Ireland	EU/1/25/1964	21.9.2026
18.9.2026	NULIBRY	Integral Pharma Solutions EU Limited 1 Windmill Lane, Dublin 2, Co. Dublin, D02 F206, Ireland	EU/1/22/1684	21.9.2026
18.9.2026	Omnitrope	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/06/332	21.9.2026
18.9.2026	Opuviz	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/24/1865	22.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
18.9.2026	Otulfi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/24/1863	23.9.2026
18.9.2026	PAVBLU	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, A96 F2A8, Ireland	EU/1/25/1909	21.9.2026
18.9.2026	Plavix	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/069	21.9.2026
18.9.2026	Replagal	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/01/189	21.9.2026
18.9.2026	Riltrava Aerosphere	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1604	21.9.2026
18.9.2026	RINVOQ	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	21.9.2026
18.9.2026	Rivaroxaban Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/21/1588	22.9.2026
18.9.2026	Roteas	Berlin-Chemie AG Glienicker Weg 125, 12489 Berlin, Deutschland	EU/1/16/1152	21.9.2026
18.9.2026	Svariya	PGF Pharma International d.o.o. Ulica Roberta Frangeša Mihanovića 9, 10110 Zagreb, Hrvatska	EU/1/25/1994	21.9.2026
18.9.2026	Tevimbra	BeOne Medicines Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	22.9.2026
18.9.2026	Tolucombi	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/821	21.9.2026
18.9.2026	TRIXEO AEROSPHERE	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1498	21.9.2026
18.9.2026	Vyepti	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/21/1599	22.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
18.9.2026	Yesafili	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/23/1751	23.9.2026
21.9.2026	Cejemly	CStone Pharmaceuticals Ireland Limited 117-126 Sheriff Street Upper Dublin 1, D01 YC43, Ireland	EU/1/24/1833	28.9.2026
21.9.2026	Daptomycin Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1175	23.9.2026
21.9.2026	ELREXFIO	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1770	22.9.2026
21.9.2026	Padcev	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1615	22.9.2026
21.9.2026	Svariya	PGF Pharma International d.o.o. Ulica Roberta Frangeša Mihanovića 9, 10110 Zagreb, Hrvatska	EU/1/25/1994	22.9.2026
21.9.2026	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	24.9.2026
25.9.2026	Briumvi	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/23/1730	6.10.2026
25.9.2026	Champix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/360	28.9.2026
25.9.2026	Humira	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/03/256	28.9.2026
25.9.2026	Imlygic	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1064	28.9.2026
25.9.2026	Lacosamide Adroiq	Extrovis EU Kft. Raktarvarosi Ut 9, Torokbalint, 2045, Magyarország	EU/1/23/1732	2.10.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
25.9.2026	Ozurdex	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/10/638	28.9.2026
25.9.2026	RIULVY	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/25/1947	6.10.2026
25.9.2026	Sialanar	Proveca Pharma Limited 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland	EU/1/16/1135	14.10.2026
25.9.2026	Usymro	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/25/1957	28.9.2026
25.9.2026	Vaxelis	MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, Nederland	EU/1/15/1079	5.10.2026
25.9.2026	Vizamyl	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/14/941	9.10.2026
25.9.2026	ZINPLAVA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/16/1156	28.9.2026
28.9.2026	Baiama	Formycon AG Fraunhoferstraße 15, 82152 Martinsried/Planegg, Deutschland	EU/1/24/1887	29.9.2026
28.9.2026	Cegfila	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland	EU/1/19/1409	29.9.2026
29.9.2026	Nexviadyme	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1579	6.10.2026

— **Irtirar ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill)

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
11.9.2026	Riluzole Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/12/768	14.9.2026

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
11.9.2026	Suboxone	Indivior Europe Limited 27 Windsor Place, Dublin 2, D02 DK44, Ireland	EU/1/06/359	17.9.2026
18.9.2026	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	22.9.2026
18.9.2026	Oslif Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/586	22.9.2026
21.9.2026	Ibandronic Acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/642	24.9.2026
21.9.2026	Xyrem	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/312	23.9.2026
28.9.2026	ZINPLAVA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/16/1156	29.9.2026

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill; L-Artikolu 5 tar-Regolament (UE) 2019/6 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
11.9.2026	Inflacam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/11/134	16.9.2026
11.9.2026	Rheumocam	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/07/078	15.9.2026
14.9.2026	Cepedex	CP Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Deutschland	EU/2/16/200	15.9.2026

Kull min jixtieq jikkonsulta r-rapport ta' evalwazzjoni pubblika dwar il-prodotti mediċinali kkonċernati u d-deċiżjonijiet marbuta magħhom għandu jikkuntattja lil:

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