ELI: http://data.europa.eu/eli/C/2026/1816/oj

Achoimre ar chinntí an Aontais Eorpaigh maidir le húdaruithe margaíochta i ndáil le táirgí íocshláinte ó 1 Feabhra 2026 go dtí 28 Feabhra 2026

(Arna fhoilsiú de bhun Airteagal 13 nó Airteagal 38 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle [1] nó Airteagal 5 de Rialachán (AE) 2019/6 ó Pharlaimint na hEorpa agus ón gComhairle [2])

(C/2026/1816)

— **Údarú margaíochta a eisiúint** (Airteagal 13 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

Dáta an chinnidh	Ainm an táirge íocshláinte	ANI (an tAinm Neamhdhílseánaigh Idirnáisiúnta)	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Foirm chógaisíochta	An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch)	Dáta an fhógra
10.2.2026	Gotenfia	golimumab	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/25/2009	Concentrate for solution for injection	L04AB06	12.2.2026
10.2.2026	Ranluspec	ranibizumab	Lupin Europe GmbH Hanauer Landstraße 139-143, 60314 Frankfurt, Deutschland	EU/1/25/2012	Solution for injection in a pre-filled syringe Tuaslagán le haghaidh insteallta	S01LA04	17.2.2026
12.2.2026	Aumseqa	aumolertinib	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/25/2006	Piolla brataithe le scannán	L01EB11	13.2.2026
12.2.2026	EXDENSUR	Depemokimab	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/25/2007	Tuaslagán le haghaidh insteallta	R03DX12	16.2.2026
12.2.2026	mNEXSPIKE	COVID-19 mRNA vaccine	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/25/2010	dispersion for injection	J07BN01	13.2.2026

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

Dáta an chinnidh	Ainm an táirge íocshláinte	ANI (an tAinm Neamhdhílseánaigh Idirnáisiúnta)	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Foirm chógaisíochta	An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch)	Dáta an fhógra
12.2.2026	MYQORZO	aficamten	Cytokinetics (Ireland) Limited 45 Mespil Rd. Dublin D04 W2F1 Ireland	EU/1/25/2014	Piolla brataithe le scannán	Pending	13.2.2026
16.2.2026	ANKTIVA	nogapendekin-alfa-inbakicept	ImmunityBio Ireland Limited 6th Floor, 2 Grand Canal Square, Dublin 2, D02 A342, Ireland	EU/1/25/2002	Concentrate for intravesical suspension	L03AC03	17.2.2026
20.2.2026	Deltyba	delamanid	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	Piolla brataithe le scannán	J04AK06	23.2.2026

ELI: http://data.europa.eu/eli/C/2026/1816/oj

— **Údarú margaíochta a mhodhnú** (Airteagal 13 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
4.2.2026	Actelsar HCT	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/13/817	6.2.2026
4.2.2026	Lytenava	Outlook Therapeutics NL B.V. Strawinskylaan 569, 1077XX Amsterdam, Nederland	EU/1/24/1798	5.2.2026
4.2.2026	Nucala	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/15/1043	5.2.2026
10.2.2026	Carbaglu	Recordati Rare Diseases Tour Hekla, 52 Avenue Du General De Gaulle, 92800 Puteaux, France	EU/1/02/246	16.2.2026
10.2.2026	Casgevy	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/23/1787	12.2.2026
10.2.2026	Emadine	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/98/095	11.2.2026
10.2.2026	Enspryng	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1559	11.2.2026
10.2.2026	JEMPERLI	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/21/1538	13.2.2026
10.2.2026	Kengrexal	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/15/994	17.2.2026
10.2.2026	Myalepta	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/18/1276	11.2.2026
10.2.2026	Relistor	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/08/463	13.2.2026
10.2.2026	Retsevmo	Eli Lilly Nederland B.V. Orteliuslaan 1000, 3528 BD, Nederland	EU/1/20/1527	11.2.2026

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
10.2.2026	Uplizna	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1602	11.2.2026
10.2.2026	Vfend	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/212	11.2.2026
12.2.2026	Akynzeo	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Ireland	EU/1/15/1001	13.2.2026
12.2.2026	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/05/315	15.2.2026
12.2.2026	Bronchitol	Pharmaxis Europe Limited 108 Q House, Furze Road, Sandyford, Dublin 18, D18AY29, Ireland	EU/1/12/760	16.2.2026
12.2.2026	Emblaveo	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/24/1808	13.2.2026
12.2.2026	EndolucinBeta	ITM Medical Isotopes GmbH Lichtenbergstraße 1, 85748 Garching/München, Deutschland	EU/1/16/1105	13.2.2026
12.2.2026	Klisyri	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/21/1558	13.2.2026
12.2.2026	Mvabea	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1445	13.2.2026
12.2.2026	Orladeyo	Biocryst Ireland Limited Block 4, Harcourt Centre, Harcourt Road, Dublin 2, D02 HW77, Ireland	EU/1/21/1544	13.2.2026
12.2.2026	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	13.2.2026
12.2.2026	Ponvory	LABORATOIRES JUVISE PHARMACEUTICALS 149 Boulevard Bataille de Stalingrad, 69100 Villeurbanne, France	EU/1/21/1550	18.2.2026

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
12.2.2026	Skyrizi	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1361	13.2.2026
12.2.2026	Veoza	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/23/1771	17.2.2026
12.2.2026	Yondelis	Pharma Mar S.A. Avenida de los Reyes 1, Polígono Industrial La Mina, 28770 Colmenar Viejo, Madrid, España	EU/1/07/417	18.2.2026
12.2.2026	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	13.2.2026
16.2.2026	Abraxane	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/428	17.2.2026
16.2.2026	SIMBRINZA	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/933	17.2.2026
16.2.2026	Strensiq	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1015	18.2.2026
16.2.2026	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	17.2.2026
16.2.2026	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	17.2.2026
18.2.2026	Busulfan Fresenius Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/14/951	19.2.2026
18.2.2026	Dimethyl fumarate Neuraxpharm	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/24/1810	23.2.2026
18.2.2026	Irbesartan Zentiva	Zentiva k.s. U kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/06/376	23.2.2026
18.2.2026	Jylamvo	Oresund Pharma ApS Orient Plads 1, 2150 Nordhavn, Danmark	EU/1/17/1172	20.2.2026

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
18.2.2026	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	19.2.2026
18.2.2026	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	19.2.2026
18.2.2026	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/98/090	19.2.2026
18.2.2026	Natpar	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/15/1078	20.2.2026
18.2.2026	Pritor	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/089	19.2.2026
18.2.2026	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	19.2.2026
20.2.2026	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	23.2.2026
23.2.2026	Afinitor	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/538	24.2.2026
23.2.2026	Atazanavir Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/19/1353	25.2.2026
23.2.2026	Balversa	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/24/1841	24.2.2026
23.2.2026	Copalia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/372	24.2.2026
23.2.2026	Dafiro	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/371	24.2.2026
23.2.2026	Evkeeza	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/21/1551	24.2.2026

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
23.2.2026	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	24.2.2026
23.2.2026	Obgemsa	PIERRE FABRE MEDICAMENT Les Cauquillous, 81500 Lavaur, France	EU/1/24/1822	2.3.2026
23.2.2026	Ravicti	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/15/1062	2.3.2026
23.2.2026	Sitagliptin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1633	25.2.2026
23.2.2026	Tabrecta	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1650	24.2.2026
23.2.2026	TAKHZYRO	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/18/1340	24.2.2026
23.2.2026	Telmisartan Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/10/639	25.2.2026
23.2.2026	Trazimera	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1295	24.2.2026
23.2.2026	Vectibix	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/07/423	24.2.2026
23.2.2026	Viagra	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/98/077	10.3.2026
23.2.2026	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/918	24.2.2026
23.2.2026	Wilzin	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/04/286	24.2.2026
25.2.2026	Bimzelx	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/21/1575	2.3.2026

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
25.2.2026	Bortezomib Fresenius Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/19/1397	26.2.2026
25.2.2026	Exforge HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/569	26.2.2026
25.2.2026	Neoatricon	BrePco Biopharma Ltd. Suite One, The Avenue, Beacon Court, Sandyford, Dublin D18HX31, Ireland	EU/1/24/1804	27.2.2026
25.2.2026	Nexium Control	Haleon Ireland Dungarvan Limited Knockbrack,Dungarvan, Co. Waterford, Ireland	EU/1/13/860	3.3.2026
25.2.2026	Nimenrix	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/767	26.2.2026
25.2.2026	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	26.2.2026
25.2.2026	Oslif Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/586	26.2.2026
25.2.2026	Strimvelis	Fondazione Telethon ETS Via Varese 16/B, 00185 Roma, Italia	EU/1/16/1097	26.2.2026
25.2.2026	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	26.2.2026
25.2.2026	Ultibro Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/862	26.2.2026
26.2.2026	Copalia HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/575	27.2.2026
26.2.2026	Dafiro HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/574	27.2.2026
26.2.2026	Exforge	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/370	27.2.2026

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
26.2.2026	Incellipan	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1807	2.3.2026
26.2.2026	Pepaxti	Oncopeptides AB (publ) Luntmakargatan 46, 111 37 Stockholm, Sverige	EU/1/22/1669	3.3.2026
26.2.2026	Thiotepa Riemser	Esteve Pharmaceuticals GmbH Hohenzollerndamm 150-151, 14199 Berlin, Deutschland	EU/1/21/1536	27.2.2026

— **Údarú margaíochta a tharraingt siar** (Airteagal 13 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle)

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
18.2.2026	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	20.2.2026
23.2.2026	Atazanavir Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/19/1353	2.3.2026
23.2.2026	Fluad Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/20/1433	24.2.2026
23.2.2026	Flucelvax Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/18/1326	25.2.2026
23.2.2026	Zegalogue	Zealand Pharma A/S Sydmarken 11, 2860 Soeborg, Danmark	EU/1/24/1829	24.2.2026

— **Údarú margaíochta a eisiúint** (Airteagal 38 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle; Airteagal 5 de Rialachán (AE) 2019/6 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

Dáta an chinnidh	Ainm an táirge íocshláinte	ANI (an tAinm Neamhdhílseánaigh Idirnáisiúnta)	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Foirm chógaisíochta	An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch)	Dáta an fhógra
25.2.2026	Lotilaner/Milbemycin Elanco	lotilaner / milbemycin oxime	Elanco GmbH Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Deutschland	EU/2/26/361	Piolla inchoganta	QP54AB51	27.2.2026

ELI: http://data.europa.eu/eli/C/2026/1816/oj

— **Údarú margaíochta a mhodhnú** (Airteagal 38 de Rialachán (CE) Uimh. 726/2004 ó Pharlaimint na hEorpa agus ón gComhairle; Airteagal 5 de Rialachán (AE) 2019/6 ó Pharlaimint na hEorpa agus ón gComhairle): **Glactha**

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
16.2.2026	Mirataz	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/19/247	23.2.2026

Aon duine ar mian leis féachaint ar an tuarascáil mheasúnaithe phoiblí maidir leis na táirgí íocshláinte atá i gceist agus na cinntí a bhaineann léi, iarrtar orthu teagmháil a dhéanamh le:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS