Achoimre ar chinntí an Aontais Eorpaigh maidir le húdaruithe margaíochta i ndáil le táirgí íocshláinte ó 1 Iúil 2025 go dtí 31 Iúil 2025

(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/2025/4668)

— **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
17.7.2025	Attrogy	Diflunisal	Purpose Pharma International AB Grev Turegatan 13b 114 46 Stockholm, Sverige	EU/1/25/1929	Piolla brataithe le scannán	NO2BA11O	18.7.2025
17.7.2025	Aucatzyl	obecabtagene autoleucel	Autolus GmbH Im Schwarzenbach 4, 79576 Weil am Rhein, Deutchland	EU/1/25/1951	Easrán le haghaidh insilte	L01XL12	18.7.2025
17.7.2025	Bomyntra	denosumab	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/25/1953	Solution for injection in a pre-filled syringe	M05BX04	18.7.2025
17.7.2025	Ezmekly	mirdametinib	SpringWorks Therapeutics Ireland Limited Hamilton House, 28 Fitzwilliam Place, Dublin 2, D02 P283, Ireland	EU/1/25/1950	Capsúl, crua Dispersible tablet	L01EE05	18.7.2025
17.7.2025	Rolcya	denosumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/25/1958	Solution for injection in a pre-filled syringe	M05BX04	24.7.2025

[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
18.7.2025	Conexxence	denosumab	Fresenius Kabi Deutschland GmbH Else-Kroener-Strasse 1, 61352 Bad Homburg von der Hoehe, Deutschland	EU/1/25/1954	Tuaslagán le haghaidh insteallta	M05BX04	22.7.2025
18.7.2025	Emtricitabine/ Tenofovir alafenamide Viatris	emtricitabine / tenofovir alafenamide	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/25/1952	Piolla brataithe le scannán	J05AR17	23.7.2025
18.7.2025	Itovebi	inavolisib	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/25/1942	Piolla brataithe le scannán	Pending	22.7.2025
23.7.2025	BLENREP	belantamab mafodotin	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/25/1948	Púdar do thiúchán do thuaslagán le haghaidh insilte	L01FX15	24.7.2025
28.7.2025	Maapliv	aimíonaigéid	Recordati Rare Diseases Tour Hekla, 52 avenue du Général de Gaulle, F-92800 Puteaux, France	EU/1/25/1955	Tuaslagán le haghaidh insilte	B05BA01	29.7.2025
28.7.2025	RIULVY	Tegomil fumarate	Neuraxpharm Pharmaceuticals, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España	EU/1/25/1947	Capsúl gastrai-fhrithsheasmhach, crua	L04AX10	7.8.2025

ELI: http://data.europa.eu/eli/C/2025/4668/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
2.7.2025	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	3.7.2025
2.7.2025	MenQuadfi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1483	3.7.2025
2.7.2025	Pemazyre	Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/21/1535	3.7.2025
7.7.2025	CARVYKTI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	8.7.2025
7.7.2025	Humira	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/03/256	8.7.2025
7.7.2025	Ozurdex	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/10/638	8.7.2025
7.7.2025	Rydapt	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1218	9.7.2025
7.7.2025	Temozolomide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/606	8.7.2025
9.7.2025	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	10.7.2025
9.7.2025	CAMZYOS	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/23/1716	15.7.2025
9.7.2025	Dovato	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/19/1370	30.7.2025
9.7.2025	Fluad	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1878	14.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
9.7.2025	Flucelvax	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/24/1879	14.7.2025
9.7.2025	Fluenz	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1816	10.7.2025
9.7.2025	HALAVEN	Eisai GmbH Edmund-Rumpler-Strasse 3, 60549 Frankfurt am Main, Deutschland	EU/1/11/678	10.7.2025
9.7.2025	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	10.7.2025
9.7.2025	Leflunomide ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/10/654	10.7.2025
9.7.2025	Nintedanib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/24/1803	10.7.2025
9.7.2025	Remsima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/13/853	16.7.2025
9.7.2025	Reyataz	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/03/267	15.7.2025
9.7.2025	Scemblix	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1670	10.7.2025
9.7.2025	Sugammadex Fresenius Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/22/1663	10.7.2025
9.7.2025	Tasmar	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/97/044	10.7.2025
9.7.2025	Tevimbra	BeOne Medicines Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/23/1758	10.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
9.7.2025	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/13/846	10.7.2025
10.7.2025	Inhixa	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077 XX Amsterdam, Nederland	EU/1/16/1132	16.7.2025
14.7.2025	Lenalidomide Krka	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/20/1519	25.7.2025
14.7.2025	Sunlenca	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/22/1671	15.7.2025
14.7.2025	Tenofovir disoproxil Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1127	16.7.2025
17.7.2025	Arsenic trioxide medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/20/1475	25.7.2025
17.7.2025	ASPAVELI	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	7.8.2025
17.7.2025	Cresemba	Basilea Pharmaceutica Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/15/1036	29.7.2025
17.7.2025	Ebglyss	Almirall S.A. Ronda General Mitre 151, 08022 Barcelona, España	EU/1/23/1765	18.7.2025
17.7.2025	Efient	SUBSTIPHARM 24 rue Erlanger, 75016 Paris, France	EU/1/08/503	18.7.2025
17.7.2025	Emtricitabine/ Tenofovir disoproxil Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1148	18.7.2025
17.7.2025	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/11/687	7.8.2025
17.7.2025	Incruse Ellipta	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/14/922	18.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
17.7.2025	Jubbonti	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/24/1813	21.7.2025
17.7.2025	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block 5, Northwood Court, Northwood Crescent, Dublin 9, D09 T665, Ireland	EU/1/20/1468	18.7.2025
17.7.2025	LIBTAYO	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/19/1376	18.7.2025
17.7.2025	Mysimba	Orexigen Therapeutics Ireland Limited 9-10 Fenian Street, Dublin 2, D02 RX24, Ireland	EU/1/14/988	21.7.2025
17.7.2025	NUBEQA	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/20/1432	25.7.2025
17.7.2025	Opdualag	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1679	22.7.2025
17.7.2025	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	21.7.2025
17.7.2025	Prolia	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/10/618	18.7.2025
17.7.2025	Tepkinly	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/23/1759	18.7.2025
17.7.2025	Verzenios	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1307	18.7.2025
17.7.2025	Voriconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/835	18.7.2025
17.7.2025	Yescarta	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/18/1299	19.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
18.7.2025	Aclasta	Sandoz Pharmaceuticals d.d. Verovškova ulica 57, 1000 Ljubljana, Slovenija	EU/1/05/308	24.7.2025
18.7.2025	Apixaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1458	24.7.2025
18.7.2025	Benlysta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/11/700	23.7.2025
18.7.2025	Darzalex	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/16/1101	23.7.2025
18.7.2025	Efavirenz/ Emtricitabine/ Tenofovir disoproxil Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/17/1210	22.7.2025
18.7.2025	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/945	23.7.2025
18.7.2025	JERAYGO	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Lörrach, Deutschland	EU/1/24/1818	22.7.2025
18.7.2025	Laventair Ellipta	GlaxoSmithKline Trading Services Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/14/899	25.7.2025
18.7.2025	Multaq	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/09/591	24.7.2025
18.7.2025	Rezolsta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/967	23.7.2025
18.7.2025	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	22.7.2025
18.7.2025	Siklos	THERAVIA 16 Rue Montrosier, 92200 Neuilly-sur-Seine, France	EU/1/07/397	22.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
18.7.2025	Supemtek Tetra	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1484	24.7.2025
18.7.2025	VEYVONDI	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/18/1298	28.7.2025
18.7.2025	VITRAKVI	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/19/1385	22.7.2025
18.7.2025	Wezenla	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/24/1823	30.7.2025
23.7.2025	CABOMETYX	Ipsen Pharma 70 rue Balard, 75015 Paris, France	EU/1/16/1136	24.7.2025
23.7.2025	Chenodeoxycholic acid Leadiant	Leadiant GmbH Liebherrstr. 22, 80538 Munich, Deutschland	EU/1/16/1110	24.7.2025
23.7.2025	Elocta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/15/1046	25.7.2025
23.7.2025	EXPAREL liposomal	Pacira Ireland Ltd Unit 13, Classon House, Dundrum Business Park, Dundrum, Dublin 14, D14W9Y3, Ireland	EU/1/20/1489	28.7.2025
23.7.2025	FRUZAQLA	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/24/1827	24.7.2025
23.7.2025	Ordspono	Regeneron Ireland Designated Activity Company (DAC) One Warrington Place, Dublin 2, D02 HH27, Ireland	EU/1/24/1843	25.7.2025
23.7.2025	Repatha	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1016	24.7.2025
23.7.2025	Trulicity	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/956	24.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
23.7.2025	Xofluza	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1500	24.7.2025
23.7.2025	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	24.7.2025
25.7.2025	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	29.7.2025
25.7.2025	Spikevax	MODERNA BIOTECH SPAIN, S.L. C/ Julián Camarillo nº 31, 28037 Madrid, España	EU/1/20/1507	29.7.2025
28.7.2025	Actraphane	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/02/229	30.7.2025
28.7.2025	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	6.8.2025
28.7.2025	Aerius	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/00/160	29.7.2025
28.7.2025	Anoro Ellipta	GlaxoSmithKline Trading Services Limited 12 River Walk, Citywest Business Campus, Dublin 24, D24 YK11, Ireland	EU/1/14/898	30.7.2025
28.7.2025	Aranesp	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/01/185	30.7.2025
28.7.2025	AYVAKYT	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/20/1473	29.7.2025
28.7.2025	Azomyr	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/00/157	29.7.2025
28.7.2025	Calquence	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1479	29.7.2025
28.7.2025	Cinryze	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/11/688	30.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
28.7.2025	Dzuveo	Laboratoire Aguettant 1 Rue Alexander Fleming, 69007 Lyon, France	EU/1/18/1284	29.7.2025
28.7.2025	Gardasil 9	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1007	29.7.2025
28.7.2025	Javlor	PIERRE FABRE MEDICAMENT Les Cauquillous, 81500 Lavaur, France	EU/1/09/550	29.7.2025
28.7.2025	Oprymea	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/469	1.8.2025
28.7.2025	Phesgo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1497	30.7.2025
28.7.2025	Qalsody	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/23/1783	30.7.2025
28.7.2025	Revestive	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/12/787	29.7.2025
28.7.2025	Spinraza	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/17/1188	29.7.2025
28.7.2025	Vyxeos liposomal	Jazz Pharmaceuticals Ireland Ltd 5th Floor, Waterloo Exchange, Waterloo Road, Dublin D04 E5W7, Ireland	EU/1/18/1308	29.7.2025
30.7.2025	ABILIFY MAINTENA	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/13/882	6.8.2025
30.7.2025	BiResp Spiromax	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/921	7.8.2025
30.7.2025	DuoResp Spiromax	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/920	7.8.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
30.7.2025	Iqirvo	Ipsen Pharma 70 rue Balard, 75015 Paris, France	EU/1/24/1855	31.7.2025
30.7.2025	Leqvio	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1494	31.7.2025
30.7.2025	Neoclarityn	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/00/161	31.7.2025
30.7.2025	Neulasta	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227	8.8.2025
30.7.2025	Orencia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/389	31.7.2025
30.7.2025	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	31.7.2025
30.7.2025	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	31.7.2025

— **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
14.7.2025	Fluenz Tetra	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/13/887	15.7.2025

— **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
4.7.2025	Innovax-ND-IBD-ILT	laryngotracheitis ionfhabhtaíoch éanúil, galar bursal ionfhabhtaíoch, vacsaín galar Marek agus galar Newcastle (athchuingreach beo)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/347	Concentrate and solvent for suspension for injection	QI01AD20	7.7.2025
24.7.2025	Numelvi	atinvicitinib	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/351	Tabléad	QD11AH93	31.7.2025
24.7.2025	Zenrelia	Ilunocitinib	Elanco GmbH Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Deutschland	EU/2/25/349	Piolla brataithe le scannán	QD11AH92	25.7.2025
30.7.2025	BRAVECTO CombiUNO	fluralaner / milbemycin oxime	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/25/350	Piolla inchoganta	QP54AB51	4.8.2025

— **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
4.7.2025	Reconcile	FORTE Healthcare Ltd Cougar Lane, Naul, Co. Dublin, Ireland	EU/2/08/080	16.7.2025
4.7.2025	Sevohale	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/16/196	7.7.2025
10.7.2025	BLUEVAC BTV	CZ Vaccines S.A.U. A Relva s/n – Torneiros 36410 O Porriño Pontevedra, España	EU/2/11/122	23.7.2025
10.7.2025	DogStem	EquiCord S.L. 103-D Loeches, Polígono Industrial Ventorro del Cano, Alcorcón, 28925 Madrid, España	EU/2/22/285	11.7.2025
24.7.2025	Bravecto	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/13/158	28.7.2025
24.7.2025	Daxocox	Ecuphar NV Legeweg 157-i, 8020 Oostkamp, België	EU/2/21/270	25.7.2025
24.7.2025	Ecoporc SHIGA	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/13/149	30.7.2025
24.7.2025	Masivet	AB Science S.A. 3 avenue George V, 75008 Paris, France	EU/2/08/087	29.7.2025
24.7.2025	Meloxidyl	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/06/070	28.7.2025
24.7.2025	Mometamax Ultra	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/22/289	28.7.2025
24.7.2025	NexGard	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/13/159	28.7.2025
24.7.2025	NEXGARD SPECTRA	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/177	28.7.2025

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
30.7.2025	Imoxat	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/21/280	1.8.2025
30.7.2025	Innovax-ND-H5	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/24/315	31.7.2025
30.7.2025	Reconcile	FORTE Healthcare Ltd Cougar Lane, Naul, Co. Dublin, Ireland	EU/2/08/080	31.7.2025

— **Údarú margaíochta a tharraingt siar** (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)

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
30.7.2025	Felisecto Plus	Zoetis Belgium SA rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/238	6.8.2025

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