C/2023/1562

29.12.2023

Achoimre ar chinntí an Aontais Eorpaigh maidir le húdaruithe margaíochta i ndáil le táirgí íocshláinte ó 1 Samhain 2023 go dtí 30 Samhain 2023

(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/2023/1562)

[1] IO L 136, 30.4.2004, lch. 1.
[2] IO L 4, 7.1.2019, lch. 43.

— **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 Neamhdhíl-seánaigh Idirnáisiúnta)	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Foirm chógaisíochta	An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch)	Dáta an fhógra
3.11.2023	Ninlaro	ixazomib	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	Capsúl, crua	L01XG03	6.11.2023
6.11.2023	VANFLYTA	quizartinib	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/23/1768	Piolla brataithe le scannán	L01EX11	7.11.2023
15.11.2023	AQUMELDI	enealapral mailéáite	Proveca Pharma Limited 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland	EU/1/23/1717	Orodispersible tablet	C09AA02	16.11.2023
15.11.2023	Catiolanze	N/A	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/23/1763	Eye drops, emulsion	S01EE01	16.11.2023
15.11.2023	Dovprela	pretomanid	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1437	Taibléad	J04AK08	16.11.2023
15.11.2023	Finlee	dabrafenib	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/23/1767	Dispersible tablet	L01EC02	16.11.2023
15.11.2023	Herwenda	trastuzumab	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/23/1762	Púdar do thiúchán do thuaslagán le haghaidh insilte	L01FD01	16.11.2023
16.11.2023	Ebglyss	lebrikizumab	Almirall S.A. Ronda General Mitre 151, 08022 Barcelona, España	EU/1/23/1765	Tuaslagán le haghaidh insteallta	Pending	17.11.2023
17.11.2023	Yorvipath	palopeg-teriparatide	Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12, DK-2900 Hellerup, Danmark	EU/1/23/1766	Tuaslagán le haghaidh insteallta	H05AA05	20.11.2023

— **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
3.11.2023	Copalia HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/575	6.11.2023
3.11.2023	Exforge HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/569	6.11.2023
3.11.2023	Jorveza	Dr Falk Pharma GmbH Leinenweberstraße 5, 79041 Freiburg im Breisgau, Deutschland	EU/1/17/1254	6.11.2023
3.11.2023	Lutetium (^{177}Lu) chloride Billev	Billev Pharma ApS Slotsmarken 10, 2970 Hørsholm, Danmark	EU/1/22/1680	6.11.2023
3.11.2023	NeoRecormon	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/97/031	6.11.2023
3.11.2023	Rizmoic	Shionogi B.V. Herengracht 464, 1017 CA, Amsterdam, Nederland	EU/1/18/1291	6.11.2023
3.11.2023	Tremelimumab AstraZeneca	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1712	6.11.2023
6.11.2023	AJOVY	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/19/1358	10.11.2023
6.11.2023	Copalia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/372	8.11.2023
6.11.2023	Dafiro	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/371	8.11.2023
6.11.2023	IDELVION	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/16/1095	9.11.2023
6.11.2023	Silodosin Recordati	Recordati Ireland Ltd Raheens East, Ringaskiddy Co. Cork P43 KD30, Ireland	EU/1/18/1343	8.11.2023
6.11.2023	Xolair	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/05/319	8.11.2023
6.11.2023	Zirabev	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1344	7.11.2023
15.11.2023	Brukinsa	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/21/1576	16.11.2023
15.11.2023	Carmustine medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/18/1278	16.11.2023

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
15.11.2023	Dafiro HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/574	16.11.2023
15.11.2023	Daxas	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/636	16.11.2023
15.11.2023	Evra	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/02/223	20.11.2023
15.11.2023	Exforge	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/370	16.11.2023
15.11.2023	Fuzeon	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/03/252	16.11.2023
15.11.2023	Harvoni	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/14/958	16.11.2023
15.11.2023	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	16.11.2023
15.11.2023	Kivexa	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/04/298	16.11.2023
15.11.2023	Miglustat Dipharma	Dipharma Arzneimittel GmbH Offheimer Weg 33, 65549 Limburg a. d. Lahn, Deutschland	EU/1/18/1346	16.11.2023
15.11.2023	Ocaliva	ADVANZ PHARMA Limited Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland	EU/1/16/1139	22.11.2023
15.11.2023	Praluent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/15/1031	16.11.2023
15.11.2023	PREVYMIS	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/17/1245	16.11.2023
15.11.2023	PREZISTA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/06/380	16.11.2023
15.11.2023	Prometax	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/092	16.11.2023
15.11.2023	Rezolsta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/967	16.11.2023
15.11.2023	Rilutek	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/96/010	16.11.2023
15.11.2023	Rubraca	pharmaand GmbH Taborstrasse 1, 1020 Wien, Österreich	EU/1/17/1250	20.11.2023
15.11.2023	Stelara	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/08/494	16.11.2023
15.11.2023	Sustiva	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/99/110	20.11.2023

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
15.11.2023	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	17.11.2023
15.11.2023	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	16.11.2023
15.11.2023	Triumeq	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/14/940	16.11.2023
15.11.2023	Trizivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/00/156	16.11.2023
15.11.2023	Vafseo	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37, 58638 Iserlohn, Deutschland	EU/1/23/1725	30.11.2023
15.11.2023	VEYVONDI	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/18/1298	16.11.2023
15.11.2023	Vyvgart	argenx BV Industriepark-Zwijnaarde 7, 9052 Gent, België	EU/1/22/1674	16.11.2023
15.11.2023	Xaluprine	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, Ireland	EU/1/11/727	16.11.2023
15.11.2023	Yuflyma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/20/1513	20.11.2023
15.11.2023	Zynlonta	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/22/1695	17.11.2023
20.11.2023	Descovy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/16/1099	22.11.2023
20.11.2023	Intelence	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/08/468	21.11.2023
20.11.2023	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/12/782	21.11.2023
20.11.2023	Lumykras	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/21/1603	21.11.2023
20.11.2023	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	21.11.2023
20.11.2023	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	21.11.2023
20.11.2023	Pelmeg	Mundipharma Corporation (Ireland) Limited United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.	EU/1/18/1328	21.11.2023

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
20.11.2023	Pirfenidone Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/22/1707	21.11.2023
20.11.2023	Roteas	Berlin-Chemie AG Glienicker Weg 125, 12489 Berlin, Deutschland	EU/1/16/1152	22.11.2023
20.11.2023	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/901	21.11.2023
20.11.2023	Ziagen	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/99/112	21.11.2023
22.11.2023	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/20/1468	23.11.2023
23.11.2023	Cufence	Univar Solutions B.V. Schouwburgplein 30, Rotterdam, 3012 CL, Nederland	EU/1/19/1365	27.11.2023
23.11.2023	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	24.11.2023
23.11.2023	PHEBURANE	Eurocept International BV Trapgans 5, 1244 RL Ankeveen, Nederland	EU/1/13/822	24.11.2023
29.11.2023	Betaferon	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/95/003	30.11.2023
29.11.2023	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	30.11.2023
29.11.2023	Eviplera	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/11/737	1.12.2023
29.11.2023	Extavia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/454	7.12.2023
29.11.2023	Lixiana	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/15/993	30.11.2023
29.11.2023	NYXTHRACIS	SFL Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/20/1485	30.11.2023
29.11.2023	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	30.11.2023
29.11.2023	Resolor	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/09/581	1.12.2023
29.11.2023	Tabrecta	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1650	4.12.2023

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
29.11.2023	Taxotere	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/95/002	1.12.2023
29.11.2023	Xermelo	SERB SAS 40 Avenue George V, 75008 Paris, France	EU/1/17/1224	4.12.2023
29.11.2023	Yesafili	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/23/1751	30.11.2023

— **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
6.11.2023	Tremelimumab AstraZeneca	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1712	7.11.2023

— **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 Neamhdhíl-seánaigh Idirnáisiúnta)	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Foirm chógaisíochta	An Cód CAT (an Cód Ceimiceach Teiripeach Anatamaíoch)	Dáta an fhógra
20.11.2023	Nobivac LoVo L4	Vacsaín leptospira chainíneach	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/23/304	Fuaidreán le haghaidh insteallta	QI07AB01	21.11.2023
20.11.2023	Senvelgo	Velagliflozin	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/23/305	Oral solution	QA10BK90	22.11.2023
23.11.2023	Bovilis Cryptium	*Cryptosporidium parvum* Gp40	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/23/303	Eibleacht le haghaidh insteallta	QI02AO02	24.11.2023

— **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
3.11.2023	Felisecto Plus	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/238	7.11.2023
20.11.2023	Tulinovet	V.M.D.n.v. Hoge Mauw 900, 2370 Arendonk, België	EU/2/20/257	21.11.2023
23.11.2023	CircoMax	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/21/281	24.11.2023
23.11.2023	FORTEKOR PLUS	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/15/185	24.11.2023
23.11.2023	Porcilis PCV ID	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/15/187	24.11.2023
23.11.2023	Suiseng Diff/A	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	27.11.2023
23.11.2023	Suvaxyn CSF Marker	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/179	27.11.2023
30.11.2023	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	4.12.2023
30.11.2023	Isemid	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/18/232	1.12.2023
30.11.2023	Kriptazen	Virbac 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	EU/2/18/234	1.12.2023
30.11.2023	Veraflox	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/10/107	1.12.2023

— **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
20.11.2023	Activyl	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/10/118	23.11.2023

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