IV

(Fógraí)

FÓGRAÍ Ó INSTITIÚIDÍ, Ó CHOMHLACHTAÍ, Ó OIFIGÍ, AGUS Ó GHNÍOMHAIREACHTAÍ AN AONTAIS EORPAIGH

AN COIMISIÚN EORPACH

Achoimre ar chinntí an Aontais Eorpaigh maidir le húdaruithe margaíochta i ndáil le táirgí íocshláinte ón 1 Nollaig 2021 go dtí an 31 Nollaig 2021

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

(2022/C 50/01)

[1] IO L 136, 30.4.2004, lch. 1.

— **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
9.12.2021	Cibinqo	abrocitinib	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/21/1593	Film-coated tablet	D11AH	10.12.2021
9.12.2021	Rybrevant	amivantamab	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	Concentrate for solution for infusion	L01FX18	10.12.2021
9.12.2021	Sitagliptin SUN	sitagliptin fumarate	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/21/1598	Film-coated tablet	A10BH01	15.12.2021
13.12.2021	ASPAVELI	pegcetacoplan	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/21/1595	Solution for infusion	L04AA54	14.12.2021
13.12.2021	Vaxneuvance	Pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/21/1591	Suspension for injection	J07AL	14.12.2021
17.12.2021	Xevudy	sotrovimab	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	Concentrate for solution for infusion	Pending	17.12.2021
20.12.2021	Nuvaxovid	COVID-19 Vaccine (recombinant, adjuvanted)	Novavax CZ, a.s. Bohumil 138, 281 63 Jevany, Česká republika	EU/1/21/1618	dispersion for injection	J07BX03	20.12.2021

— **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
2.12.2021	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	3.12.2021
2.12.2021	Ebilfumin	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/14/915	7.12.2021
2.12.2021	Ivozall	ORPHELIA Pharma SAS 85 boulevard Saint-Michel, 75005 Paris, France	EU/1/19/1396	7.12.2021
2.12.2021	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	3.12.2021
2.12.2021	Revinty Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/929	3.12.2021
3.12.2021	Kiovig	Baxter AG Industriestraße 67, 1221 Wien, Österreich	EU/1/05/329	6.12.2021
3.12.2021	Lojuxta	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/13/851	15.12.2021
3.12.2021	Naglazyme	BioMarin International Limited Shanbally, Ringaskiddy, County Cork P43 R298, Ireland	EU/1/05/324	11.1.2022
3.12.2021	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	6.12.2021
3.12.2021	Polivy	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/19/1388	7.12.2021
3.12.2021	Xagrid	Takeda Pharmaceuticals International AG Ireland Branch 50-58 Baggot Street Lower, Block 3 Miesian Plaza, Dublin 2, Co Dublin, D02 Y754, Ireland	EU/1/04/295	6.12.2021
6.12.2021	RoActemra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/08/492	7.12.2021
7.12.2021	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	7.12.2021
8.12.2021	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	8.12.2021
9.12.2021	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbæk Strand, Danmark	EU/1/12/794	14.12.2021

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
9.12.2021	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	13.12.2021
9.12.2021	Amyvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/12/805	13.12.2021
9.12.2021	Apealea	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/18/1292	10.12.2021
9.12.2021	Chenodeoxycholic acid Leadiant	Leadiant GmbH Liebherrstr. 22, 80538 Munich, Deutschland	EU/1/16/1110	10.12.2021
9.12.2021	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	10.12.2021
9.12.2021	Dengvaxia	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/18/1338	13.12.2021
9.12.2021	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	10.12.2021
9.12.2021	Esbriet	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/11/667	10.12.2021
9.12.2021	Exelon	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/066	10.12.2021
9.12.2021	Holoclar	Holostem Terapie Avanzate S.r.l. Via Glauco Gottardi 100, Modena, MO 41125, Italia	EU/1/14/987	13.12.2021
9.12.2021	JETREA	Inceptua AB Gustavslundsv. 143, 16751 Bromma, Sverige	EU/1/13/819	10.12.2021
9.12.2021	Leganto	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/11/695	10.12.2021
9.12.2021	Livogiva	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/20/1462	13.12.2021
9.12.2021	Ogluo	Tetris Pharma B.V Element Offices, Bargelaan 180-200, 2333 CW, Leiden, Nederland	EU/1/20/1523	13.12.2021
9.12.2021	Pioglitazone Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/722	10.12.2021

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
9.12.2021	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	14.12.2021
9.12.2021	Roteas	Berlin-Chemie AG Glienicker Weg 125, 12489 Berlin, Deutschland	EU/1/16/1152	15.12.2021
9.12.2021	Stalevo	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/03/260	10.12.2021
9.12.2021	Thalidomide BMS	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/08/443	10.12.2021
9.12.2021	Xospata	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/19/1399	10.12.2021
9.12.2021	ZALTRAP	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/12/814	10.12.2021
9.12.2021	Zyprexa	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/96/022	13.12.2021
9.12.2021	Zyprexa Velotab	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/99/125	13.12.2021
13.12.2021	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbæk Strand, Danmark	EU/1/12/794	14.12.2021
13.12.2021	Conbriza	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/09/511	14.12.2021
13.12.2021	Giotrif	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/13/879	14.12.2021
13.12.2021	Invanz	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/02/216	14.12.2021
13.12.2021	Kanuma	Alexion Europe SAS 103-105 rue Anatole France, 92300 Levallois-Perret, France	EU/1/15/1033	14.12.2021
13.12.2021	Kinzalmono	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/98/091	14.12.2021
13.12.2021	Mycophenolate mofetil Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/07/439	14.12.2021
13.12.2021	Neulasta	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227	15.12.2021
13.12.2021	Neuraceq	Life Radiopharma Berlin GmbH Max-Planck-Straße 4, 12489 Berlin, Deutschland	EU/1/13/906	15.12.2021

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
13.12.2021	NULOJIX	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/11/694	14.12.2021
13.12.2021	Pramipexole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/728	16.12.2021
13.12.2021	Pramipexole Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/08/490	17.12.2021
13.12.2021	Rapiscan	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/10/643	15.12.2021
13.12.2021	Rebif	Merck Europe B.V. Gustav Mahlerplein 102, Ito Toren, 1082 MA Amsterdam, Nederland	EU/1/98/063	17.12.2021
13.12.2021	Rivastigmine Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/09/599	15.12.2021
13.12.2021	Thalidomide BMS	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/08/443	14.12.2021
13.12.2021	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	15.12.2021
16.12.2021	Ceprotin	Baxter AG Industriestraße 67, 1221 Wien, Österreich	EU/1/01/190	17.12.2021
16.12.2021	Cinacalcet Accordpharma	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1429	17.12.2021
16.12.2021	Clopidogrel Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	20.12.2021
16.12.2021	Clopidogrel Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/08/465	23.12.2021
16.12.2021	COVID-19 Vaccine Janssen	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1525	16.12.2021
16.12.2021	Dexdor	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/718	19.12.2021
16.12.2021	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	17.12.2021
16.12.2021	Herzuma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/17/1257	20.12.2021
16.12.2021	Humira	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/03/256	17.12.2021

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
16.12.2021	Jyseleca	Galapagos NV Generaal De Wittelaan L11 A3, 2800 Mechelen Antwerp, België	EU/1/20/1480	17.12.2021
16.12.2021	KANJINTI	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/18/1281	20.12.2021
16.12.2021	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	20.12.2021
16.12.2021	Revestive	Shire Pharmaceuticals Ireland Limited Blocks 2 & 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/12/787	23.12.2021
16.12.2021	Rinvoq	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	17.12.2021
16.12.2021	Sarclisa	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/20/1435	17.12.2021
16.12.2021	Siklos	Addmedica 37 rue de Caumartin, 75009 Paris, France	EU/1/07/397	17.12.2021
16.12.2021	Vemlidy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/16/1154	17.12.2021
16.12.2021	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	17.12.2021
16.12.2021	Zoely	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/11/690	21.12.2021
16.12.2021	Zoely	Theramex Ireland Limited 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland	EU/1/11/690	21.12.2021
17.12.2021	Kineret	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/02/203	17.12.2021
20.12.2021	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/15/1040	21.12.2021
20.12.2021	Nitisinone MDK	MendeliKABS Europe Limited Unit 3D, North Point House, North Point Business Park, New Mallow Road 9, Cork, T23 AT2P, Ireland	EU/1/17/1217	21.12.2021

Dáta an chinnidh	Ainm an táirge íocshláinte	Sealbhóir an údaraithe margaíochta	Uimhir na hiontrála sa Chlár Comhphobail	Dáta an fhógra
20.12.2021	PANTOLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/519	21.12.2021
20.12.2021	Raloxifene Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/627	23.12.2021
20.12.2021	Selincro	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/12/815	21.12.2021
20.12.2021	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	20.12.2021
20.12.2021	Voriconazole Hikma	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó n.º 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal	EU/1/15/1004	4.1.2022

— **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
13.12.2021	Leganto	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/11/695	4.1.2022
20.12.2021	PANTOLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/519	21.12.2021
20.12.2021	Rasilez HCT	Noden Pharma DAC D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland	EU/1/08/491	22.12.2021
20.12.2021	Ytracis	CIS bio international Boite Postale 32, 91192 Gif-sur-Yvette, France	EU/1/03/250	22.12.2021

— **Údarú margaíochta a eisiúint** (Airteagal 38 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
7.12.2021	Imoxat	imidacloprid/ moxidectin	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/21/280	Spot-on solution	QP54AB52	9.12.2021
7.12.2021	Suiseng Diff/A	Clostridioides difficile and Clostridium perfringens vaccine, inactivated	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	Suspension for injection	QI09AB12	9.12.2021
15.12.2021	Zenalpha	medetomidine hydrochloride/ vatinoxan hydrochloride	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/21/279	Solution for injection	QN05CM99	16.12.2021

— **Údarú margaíochta a mhodhnú** (Airteagal 38 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
7.12.2021	Circovac	CEVA-Phylaxia Co. Ltd Szállás u. 5, 1107 Budapest, Magyarország	EU/2/07/075	9.12.2021
7.12.2021	Stronghold Plus	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	13.12.2021
13.12.2021	Apoquel	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	15.12.2021
15.12.2021	Bravecto Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/18/224	16.12.2021
15.12.2021	Cardalis	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/12/142	16.12.2021
15.12.2021	Osurnia	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/14/170	16.12.2021
15.12.2021	Rabitec	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/219	16.12.2021

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