

OFFERYNNAU STATUDOL CYMRU

WELSH STATUTORY INSTRUMENTS

2020 Rhif 1396 (Cy. 309)

YMADAEL Â'R UNDEB EWROPEAIDD, CYMRU

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc.) (Cymru) (Diwygio) (Ymadael â'r UE) 2020

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

Mae'r Rheoliadau hyn wedi eu gwneud drwy arfer y pwerau ym mharagraff 1(1) o Atodlen 2 i Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 (p. 16), er mwyn ymdrin ag unrhyw fethiant yng nghyfraith yr UE a ddargedwir i weithredu'n effeithiol a diffygion eraill sy'n deillio o ymadawiad y Deyrnas Unedig â'r Undeb Ewropeaidd.

Mae'r Rheoliadau yn diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc.) (Cymru) 2004.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol cynnal asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

2020 No. 1396 (W. 309)

EXITING THE EUROPEAN UNION, WALES

NATIONAL HEALTH SERVICE, WALES

The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in paragraph 1(1) of Schedule 2 to the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

The Regulations make amendments to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

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EXITING THE EUROPEAN UNION, WALES

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NATIONAL HEALTH SERVICE, WALES

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc.) (Cymru) (Diwygio) (Ymadael â'r UE) 2020 The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020

Gofynion bodloni	sifftio 10	wedi 6 Tachwed	eu dd 2020
Gwnaed		1 Rhagf	yr 2020
Gosodwyd Cymru	gerbron	2 Rhagf	Senedd Syr 2020

Sift requirements satisfied 16 November 2020

1 December 2020

Laid before Senedd Cymru 2 December 2020

Made

Yn dod i rym yn unol â rheoliad 1(2)

Coming into force in accordance with regulation 1(2)

Mae Gweinidogion Cymru yn gwneud y Rheoliadau hyn drwy arfer y pwerau a roddir gan baragraff 1(1) o Atodlen 2 a pharagraff 21 o Atodlen 7 i Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018(1).

The Welsh Ministers make these Regulations in exercise of the powers conferred by paragraph 1(1) of Schedule 2 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018(1).

Mae gofynion paragraff 4(2) o Atodlen 7 i'r Ddeddf honno (sy'n ymwneud â'r weithdrefn graffu briodol ar gyfer y Rheoliadau hyn) wedi eu bodloni. The requirements of paragraph 4(2) of Schedule 7 to that Act (relating to the appropriate scrutiny procedure for these Regulations) have been satisfied.

Fel sy'n ofynnol gan baragraff 4(a) o Atodlen 2 i Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018, ymgynghorwyd â'r Ysgrifennydd Gwladol wrth lunio'r Rheoliadau hyn.

As required by paragraph 4(a) of Schedule 2 to the European Union (Withdrawal) Act 2018, the Secretary of State has been consulted during the preparation of these Regulations.

^{(1) 2018} p. 16. Diwygiwyd Atodlen 2 gan adran 27 o Ddeddf yr Undeb Ewropeaidd (Y Cytundeb Ymadael) 2020 (p. 1).

^{(1) 2018} c. 16. Schedule 2 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1).

Enwi, cychwyn a chymhwyso

- 1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc.) (Cymru) (Diwygio) (Ymadael â'r UE)
- (2) Daw'r Rheoliadau hyn i rym yn union cyn diwrnod cwblhau'r cyfnod gweithredu.
 - (3) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc.) (Cymru) 2004

- **2.**—(1) Mae Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc.) (Cymru) 2004(1) wedi eu diwygio fel a ganlyn.
- (2) Yn Atodlen 2 (cyffuriau neu feddyginiaethau i'w harchebu o dan amgylchiadau penodol yn unig), yn y cofnod yng ngholofn 2 o'r tabl sy'n cyfateb i'r cofnod yng ngholofn 1 sy'n ymwneud â chyffuriau ar gyfer trin camweithredu ymgodol—
 - (a) yn lle paragraff (1)(b) (gan gynnwys yr "or" ar y diwedd) rhodder—
 - "(b) a man who is a national of an EEA State who—
 - (i) immediately before IP completion day was entitled to treatment by virtue of Article 7(2) of Council Regulation 1612/68 as extended by the EEA Agreement or was entitled to treatment by virtue of any other enforceable EU right,
 - (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment under a national health insurance system of an EEA State for that condition with any of the drugs listed in subparagraph (a), and
 - (iii) immediately before IP completion day was receiving a course of treatment as part of the health service for the

Title, commencement and application

- 1.—(1) The title of these Regulations is the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020.
- (2) These Regulations come into force immediately before IP completion day.
 - (3) These Regulations apply in relation to Wales.

Amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004

- **2.**—(1) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004(1) are amended as follows.
- (2) In Schedule 2 (drugs or medicines to be ordered only in certain circumstances), in the entry in column 2 of the table that corresponds to the entry in column 1 relating to drugs for the treatment of erectile dysfunction—
 - (a) for paragraph (1)(b) (including the "or" at the end) substitute—
 - "(b) a man who is a national of an EEA State who—
 - (i) immediately before IP completion day was entitled to treatment by virtue of Article 7(2) of Council Regulation 1612/68 as extended by the EEA Agreement or was entitled to treatment by virtue of any other enforceable EU right,
 - (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment under a national health insurance system of an EEA State for that condition with any of the drugs listed in subparagraph (a), and
 - (iii) immediately before IP completion day was receiving a course of treatment as part of the health service for the

⁽¹⁾ O.S. 2004/1022 (Cy. 119); gwnaed diwygiadau perthnasol gan O.S. 2011/1043, O.S. 2014/109 (Cy. 09) ac O.S. 2019/777.

⁽¹⁾ S.I. 2004/1022 (W. 119); relevant amendments were made by S.I. 2011/1043, S.I. 2014/109 (W. 09) and S.I. 2019/777.

condition mentioned in paragraph (ii) of this subparagraph with any of the drugs listed in subparagraph (a), or"; a

- (b) yn lle paragraff (c) (gan gynnwys yr "or" ar y diwedd) rhodder
 - "(c) a man who is not a national of an EEA State but who is the member of the family of such a national and who—
 - (i) immediately before IP completion day had an enforceable EU right to be treated no less favourably than the national in the provision of medical treatment,
 - (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment for that condition with any of the drugs listed in sub-paragraph (a), and
 - (iii) immediately before completion day was receiving a course of treatment as part of the service health for condition mentioned paragraph (ii) of this subparagraph with any of the drugs listed in paragraph (a), or".

condition mentioned in paragraph (ii) of this subparagraph with any of the drugs listed in subparagraph (a), or"; and

- (b) for paragraph (c) (including the "or" at the end) substitute
 - "(c) a man who is not a national of an EEA State but who is the member of the family of such a national and who—
 - (i) immediately before IP completion day had an enforceable EU right to be treated no less favourably than the national in the provision of medical treatment,
 - (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment for that condition with any of the drugs listed in sub-paragraph (a), and
 - (iii) immediately before IP completion day was receiving a course of treatment as part of the health service for the condition mentioned paragraph (ii) of this subparagraph with any of the drugs listed in subparagraph (a), or".

Vaughan Gething

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru 1 Rhagfyr 2020

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