

CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2005 Rhif 366 (Cy.32)

2005 No. 366 (W.32)

Y GWASANAETH IECHYD GWLADOL, CYMRU

NATIONAL HEALTH SERVICE, WALES

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2005 The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2005

NODYN ESBONIADOL

EXPLANATORY NOTE

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

(This note is not part of the Regulations)

Mae'r Rheoliadau hyn yn diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc) (Cymru) 2004 ("y prif Reoliadau") sy'n gwneud darpariaethau ynghylch y cyffuriau, y meddyginiaethau neu'r sylweddau eraill y caniateir eu harchebu ar gyfer cleifion wrth ddarparu gwasanaethau meddygol o dan gontract gwasanaethau meddygol cyffredinol o fewn ystyr "general medical services contract" yn adran 28Q o Ddeddf y Gwasanaeth Iechyd Gwladol 1977.

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 ("the principal Regulations") which make provisions as to the drugs, medicines or other substances that may be ordered for patients in the provision of medical services under a general medical services contract within the meaning of section 28Q of the National Health Service Act 1977.

Mae rheoliad 2 yn ychwanegu Oseltamivir (Tamiflu) a Zanamivir (Relenza) at Atodlen 2 i'r prif Reoliadau, sy'n rhestru'r cyffuriau a'r sylweddau eraill y caniateir eu harchebu o dan gontract o'r fath o dan amgylchiadau penodol yn unig, ac mae'n nodi o dan ba amgylchiadau y caniateir eu harchebu.

Regulation 2 adds Oseltamivir (Tamiflu) and Zanamivir (Relenza) to Schedule 2 to the principal Regulations, which lists the drugs and other substances that may be ordered under such a contract only in certain circumstances, and sets out the circumstances in which they may be ordered.

2005 Rhif 366 (Cy.32)

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2005

Wedi'u gwneud 22 Chwefror 2005 Yn dod i rym 4 Ebrill 2005

Mae Cynulliad Cenedlaethol Cymru, drwy arfer y pwerau a roddwyd gan adrannau 28U a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977(1) drwy hyn yn gwneud y Rheoliadau canlynol:

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) 2005 a deuant i rym ar 4 Ebrill 2005.
- (2) Mae'r Rheoliadau hyn yn gymwys o ran Cymru yn unig.

2005 No. 366 (W.32)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2005

Made 22 February 2005

Coming into force 4 April 2005

The National Assembly for Wales, in exercise of the powers conferred by sections 28U and 126(4) of the National Health Service Act 1977(1) hereby makes the following Regulations:

Citation, commencement, and application

- 1.-(1) These Regulations are called the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2005 and come into force on 4 April 2005.
- (2) These Regulations apply in relation to Wales only.

Diwygiwyd adran 126(4) gan Ddeddf y Gwasanaeth Iechyd Gwladol a Gofal Cymunedol 1990 (p.19), adran 65(2) a chan Ddeddf Iechyd 1999 (p.8), Atodlen 4, paragraff 37(6).

Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan adrannau 28U a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977 i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999, O.S. 1999/672, erthygl 2 ac Atodlen 1, fel y'i diwygiwyd gan Ddeddf 1999, adran 66(5).

Section 126(4) was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2) and the Health Act 1999 (c.8), Schedule 4, paragraph 37(6).

The functions of the Secretary of State under sections 28U and 126(4) of the National Health Service Act 1977 were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, S.I.1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(5).

^{(1) 1977} p.49; mewnosodwyd adran 28U gan adran 175(1) o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003 (p.43); y dyddiad y daeth i rym: 28/2/04; gweler O.S. 2004/480, erthygl 3(1)(a).

^{(1) 1977} c.49; section 28U was inserted by section 175(1) of the Health and Social Care (Community Health and Standards) Act 2003 (c.43); date in force 28/2/04 see S.I 2004/480, article 3(1)(a).

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

- 2.-(1) Mae Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) 2004(1) yn cael eu diwygio fel a ganlyn.
- (2) Yn Atodlen 2 (cyffuriau neu feddyginiaethau i'w harchebu o dan amgylchiadau penodol yn unig)-
 - (a) Yn y man priodol ac yn nhrefn yr wyddor yn ôl enw'r cyffur, mewnosoder yng ngholofnau 1, 2 a 3 yn y drefn honno-

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

- 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)-
 - (a) In the appropriate place in the alphabetical order having regard to the name of the drug, insert in columns 1, 2 and 3 respectively-

Treatment of

influenza

| "Oseltamivir | (1) At-risk adult and | Treatment of | "Oseltamivir | (1) At-risk adult and |
|--------------|--|-----------------------------------|--------------|--|
| (Tamiflu) | child patients where - | influenza | (Tamiflu) | child patients where - |
| | (a) It has been determined in accordance with a community based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating; | | | (a) It has been determined in accordance with a community based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating; |
| | (b) the patient has an influenza-like illness; and | | | (b) the patient has an influenza-like illness; and |
| | (c) the patient can start therapy within 48 hours of the onset of symptoms. | | | (c) the patient can start therapy within 48 hours of the onset of symptoms. |
| | (2) At-risk patients who are aged 13 years and older where - | Prophylaxis of infinfluenza | | (2) At-risk patients who are aged 13 years and older where - |
| | (a) it has been determined in accordance with a community-based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides; | | | (a) it has been determined in accordance with a community-based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides; |

| circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating; | |
|--|-----------------------------------|
| (b) the patient has an influenza-like illness; and | |
| (c) the patient can start therapy within 48 hours of the onset of symptoms. | |
| (2) At-risk patients who are aged 13 years and older where - | Prophylaxis of infinfluenza |
| (a) it has been determined in accordance with a community-based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides; | |

⁽¹⁾ S.I.2004/1022 (W.119).

- (b) the patient has been exposed to an influenza-like illness as a result of being in close contact with someone with whom the patient lives who is, or has been, suffering from an influenza-like illness;
- (c) the patient is not effectively protected by vaccination against influenza because the patient -
- (i) has not been vaccinated because vaccination is contra-indicated;
- (ii) has not been vaccinated since the previous vaccination season;
- (iii) has been vaccinated but the vaccination has yet to take effect; or
- (iv) the patient has been vaccinated but the vaccine is not well matched to the strain of influenza circulating in the locality in which the patient resides or is or has been present;
- (d) the patient lives in a residential care establishment and another resident or member of staff of the establishment has an influenza-like illness; and
- (e) the patient can start prophylaxis within 48 hours of exposure to an influenza-like illness.

- (b) the patient has been exposed to an influenza-like illness as a result of being in close contact with someone with whom the patient lives who is, or has been, suffering from an influenza-like illness;
- (c) the patient is not effectively protected by vaccination against influenza because the patient -
- (i) has not been vaccinated because vaccination is contra-indicated;
- (ii) has not been vaccinated since the previous vaccination season;
- (iii) has been vaccinated but the vaccination has yet to take effect; or
- (iv) the patient has been vaccinated but the vaccine is not well matched to the strain of influenza circulating in the locality in which the patient resides or is or has been present;
- (d) the patient lives in a residential care establishment and another resident or member of staff of the establishment has an influenza-like illness; and
- (e) the patient can start prophylaxis within 48 hours of exposure to an influenza-like illness.

"; and

"; a

| "Zanamivir (Relenza) | At-risk adult patients where- | Treatment of influenza |
|-------------------------|---|------------------------|
| | (a) it has been determined in accordance with a community based virological surveillance scheme that influenza A and influenza B is circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating; | |
| | (b) the patient has an influenza-like illness; and | |
| | (c) the patient can start therapy within 48 hours of the onset of the symptoms. | ". |

| "Zanamivir (Relenza) | At-risk adult patients where- | Treatment of influenza |
|-------------------------|---|------------------------|
| | (a) it has been determined in accordance with a community based virological surveillance scheme that influenza A and influenza B is circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating; | |
| | (b) the patient has an influenza-like illness; and | |
| | (c) the patient can start therapy within 48 hours of the onset of the symptoms. | ". |

- (b) Ar ôl y geiriau "in this Schedule" mewnosoder yn y man priodol yn nhrefn yr wyddor-
- " "at-risk" means an adult or child patient or a patient aged 13 years or older who-
 - (a) has chronic respiratory disease (including asthma and chronic obstructive pulmonary disease);
 - (b) has significant cardiovascular disease, excluding an adult or child patient who has hypertension only;
 - (c) has chronic renal disease;
 - (d) is immunocompromised;
 - (e) has diabetes mellitus; or
 - (f) is aged 65 years or over; ";
- " "child" means any person under the age of 16 years;";
- " "patient" has the same meaning as in the National Health Services (General Medical Services Contracts) (Wales) Regulations 2004(1);"; a
- " "residential care establishment" means a place where persons reside on a long-term basis in order to receive continuing care.".

- (b) After the words "in this Schedule" insert in the appropriate place in the alphabetical order-
- " "at-risk" means an adult or child patient or a patient aged 13 years or older who-
 - (a) has chronic respiratory disease (including asthma and chronic obstructive pulmonary disease);
 - (b) has significant cardiovascular disease, excluding an adult or child patient who has hypertension only;
 - (c) has chronic renal disease;
 - (d) is immunocompromised;
 - (e) has diabetes mellitus; or
 - (f) is aged 65 years or over; ";
- " "child" means any person under the age of 16 years;";
- " "patient" has the same meaning as in the National Health Services (General Medical Services Contracts) (Wales) Regulations 2004(1);"; and
- " "residential care establishment" means a place where persons reside on a long-term basis in order to receive continuing care.".

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(1)

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(1)

22 Chwefror 2005 22 February 2005

D. Elis-Thomas

Llywydd y Cynulliad Cenedlaethol

The Presiding Officer of the National Assembly

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Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2005 2005 No. 366 (W.32)

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