
OFFERYNNAU STATUDOL CYMRU

2013 Rhif 683 (Cy. 81)

Y GWASANAETH IECHYD GWLADOL, CYMRU

**Rheoliadau'r Gwasanaeth Iechyd Gwladol
(Contractau Gwasanaethau Meddygol Cyffredinol)
(Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2013**

<i>Gwnaed</i>	- - - -	<i>21 Mawrth 2013</i>
<i>Gosodwyd gerbron Cynulliad</i>		
<i>Cenedlaethol Cymru</i>	- -	<i>22 Mawrth 2013</i>
<i>Yn dod i rym</i>	- -	<i>12 Ebrill 2013</i>

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddwyd gan adrannau 46(2), 203(9) a (10) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(1), yn gwneud y Rheoliadau a ganlyn:

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) 2013, a deuant i rym ar 12 Ebrill 2013.

(2) 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(2) wedi eu diwygio fel a ganlyn.

(2) Yn Atodlen 2 (cyffuriau neu feddyginiaethau i'w harchebu o dan amgylchiadau penodol yn unig)—

(a) yn y cofnod am y cyffur Oseltamir (Tamiflu), yn lle'r cofnodion yng ngholofnau 2 a 3, yn eu trefn, rhodder—

“(1) A patient who is aged 1 year or over Treatment of influenza
and who is at clinical risk or a patient who is

(1) 2006 p.42.

(2) O.S. 2004/1022 (Cy.119); mae'r Rheoliadau hyn wedi eu diwygio gan O.S. 2005/366 (Cy.32), O.S. 2009/1977 (Cy.176), O.S. 2009/1838 (Cy.166), O.S. 2011/1043, ac O.S. 2012/1916.

pregnant or aged 65 years or over, or who is aged under 65 years and is at risk of developing medical complications for influenza, where—

- (a) the Welsh Ministers have notified general medical practitioners that the influenza virus is circulating in the community;
- (b) the patient has an influenza-like illness; and
- (c) the patient can start therapy within 48 hours of the onset of symptoms.

(2) A patient who is aged 1 year or over and who is at clinical risk or a patient who is pregnant or aged 65 years or over, or who is aged under 65 years and is at risk of developing medical complications for influenza, 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;
- (b) the patient has an influenza-like illness; and
- (c) the patient can start therapy within 48 hours of the onset of symptoms.

(3) Any patient suffering from influenza during an outbreak of pandemic influenza (influenza caused by a new virus subtype that has an increased and sustained transmission during a global outbreak of influenza), where the drug is ordered under arrangements for the distribution of the drug free of charge which are approved by the Welsh Ministers.

(4) A patient who is aged 1 year or over and who is at clinical risk or a patient who is pregnant or aged 65 years or over, where—

- (a) the Welsh Ministers have notified general medical practitioners that the influenza virus is circulating in the community;
- (b) the patient has been exposed to an influenza-like illness through being in close contact with someone with whom he lives who is or has been suffering from an influenza-like illness;

Prophylaxis of influenza”

- (c) the patient is not effectively protected by vaccination against influenza because—
 - (i) he has not been vaccinated because vaccination is contraindicated;
 - (ii) he has not been vaccinated since the previous influenza season;
 - (iii) he has been vaccinated but it has yet to take effect; or
 - (iv) he 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.
- (5) A patient who is aged 1 year or over and who is at clinical risk or a patient who is pregnant or aged 65 years or over, 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;
 - (b) the patient has been exposed to an influenza-like illness through being in close contact with someone with whom he lives who is or has been suffering from an influenza-like illness;
 - (c) the patient is not effectively protected by vaccination against influenza because—
 - (i) he has not been vaccinated because vaccination is contraindicated;

- (ii) he has not been vaccinated since the previous influenza season;
- (iii) he has been vaccinated but it has yet to take effect; or
- (iv) he 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.

(6) Any patient at risk from influenza during an outbreak of pandemic influenza (influenza caused by a new virus subtype that has an increased and sustained transmission during a global outbreak of influenza), where the drug is ordered under arrangements for the distribution of the drug free of charge which are approved by the Welsh Ministers.

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- (b) yn y cofnod am gyffuriau ar gyfer trin camweithredu ymgodol yng ngholofn 2, ar ôl paragraff (f) mewnosoder—

“(g) a man who has been diagnosed as suffering severe distress resulting from erectile dysfunction where the assessment has been made by a specialist service or GP under arrangements made with a Local Health Board to provide such assessments”.

- (c) yn y cofnod am y cyffur Zanamivir (Relenza), yn lle'r cofnodion yng ngholofnau 2 a 3, yn eu trefn, rhodder—

“(1) A patient who is aged 5 years or over Treatment of influenza and who is at clinical risk or a patient who is pregnant or aged 65 years or over, or who is aged under 65 years and is at risk of developing medical complications from influenza, where—

- (a) the Welsh Ministers have notified general medical practitioners that the influenza virus is circulating in the community;
- (b) the patient has an influenza-like illness; and
- (c) in the case of a patient—

- (i) who has attained the age of 5 years but not the age of 13 years, that patient can start therapy within 36 hours of the onset of symptoms;
- (ii) who is aged 13 years or over, that patient can start therapy within 48 hours of the onset of symptoms.

(2) A patient who is aged 5 years or over and who is at clinical risk or a patient who is pregnant or aged 65 years or over, or who is aged under 65 years and is at risk of developing medical complications from influenza 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 was present at the time that the virus was circulating;
- (b) the patient has an influenza-like illness; and
- (c) in the case of a patient—
 - (i) who has attained the age of 5 years but not the age of 13 years, that patient can start therapy within 36 hours of the onset of symptoms;
 - (ii) who is aged 13 years or over, that patient can start therapy within 48 hours of the onset of symptoms.

Any patient at risk of or suffering from influenza during an outbreak of pandemic influenza (influenza caused by a new virus subtype that has an increased and sustained transmission during a global outbreak of influenza), where the drug is ordered under arrangements for the distribution of the drug free of charge which are approved by the Welsh Ministers.

Prophylaxis or treatment of influenza”

Statws *This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.*

21 Mawrth 2013

Mark Drakeford
Y Gweinidog Iechyd a Gwasanaethau
Cymdeithasol, un o Weinidogion Cymru

EXPLANATORY NOTE

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

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 darpariaeth o ran y cyffuriau, meddyginiaethau neu sylweddau eraill y caniateir eu harchebu ar gyfer cleifion wrth ddarparu gwasanaethau meddygol o dan gontract gwasanaethau meddygol cyffredinol o fewn ystyr adran 42 o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006.

Mae rheoliad 2 yn diwygio Atodlen 2 i'r prif Reoliadau (cyffuriau neu feddyginiaethau i'w harchebu o dan rai amgylchiadau yn unig) er mwyn ychwanegu amgylchiadau pellach pryd y caniateir archebu rhai cyffuriau o dan gontract o'r fath. Y cyffuriau dan sylw yw Oseltamir (Tamiflu), Alprostadil (Caverject), (MUSE), (Viridal), Apomorphine Hydrochloride (Uprima), Moxisylyte Hydrochloride (Erecnos), Sildenafil (Viagra), Tadalafil (Cialis), Thymoxamine Hydrochloride (Erecnos), Vardenafil (Levitra), a'r cyffur Zanamivir (Relenza).

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar wneud Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol gwneud asesiad effaith rheoleiddiol o gostau a buddion tebygol cydymffurfio â'r Rheoliadau hyn.