



OFFERYNNAU STATUDOL
CYMRU

WELSH STATUTORY
INSTRUMENTS

2013 Rhif 683 (Cy. 81)

2013 No. 683 (W. 81)

**Y GWASANAETH IECHYD
GWLADOL, CYMRU**

**NATIONAL HEALTH
SERVICE, WALES**

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

The National Health Service
(General Medical Services
Contracts) (Prescription of Drugs
Etc.) (Wales) (Amendment)
Regulations 2013

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 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.

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 ("the principal Regulations") which make provision 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 42 of the National Health Service (Wales) Act 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).

Regulation 2 amends Schedule 2 to the principal Regulations (drugs or medicines to be ordered only in certain circumstances) to add further circumstances in which certain drugs may be ordered under such a contract. The drugs in question are Oseltamir (Tamiflu), Alprostadil (Caverject), (MUSE), (Viridal), Apomorphine Hydrochloride (Uprima), Moxisylyte Hydrochloride (Erecnos), Sildenafil (Viagra), Tadalafil (Cialis), Thymoxamine Hydrochloride (Erecnos), Vardenafil (Levitra), and the drug 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.

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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**NATIONAL HEALTH
SERVICE, WALES**

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

The National Health Service
(General Medical Services
Contracts) (Prescription of Drugs
Etc.) (Wales) (Amendment)
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Gwnaed 21 Mawrth 2013
*Gosodwyd gerbron Cynulliad
Cenedlaethol Cymru* 22 Mawrth 2013
Yn dod i rym 12 Ebrill 2013

Made 21 March 2013
*Laid before the National
Assembly for Wales* 22 March 2013
Coming into force 12 April 2013

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:

The Welsh Ministers, in exercise of the powers conferred by sections 46(2), 203(9) and (10) of the National Health Service (Wales) Act 2006(1), make the following Regulations:

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)—

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) Regulations 2013 and they come into force on 12 April 2013.

(2) 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(2) are amended as follows.

(2) In Schedule 2 (drugs or medicines to be ordered only in certain circumstances)—

(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.

(1) 2006 c.42.

(2) S.I. 2004/1022 (W.119); these Regulations have been amended by S.I. 2005/366 (W.32), S.I. 2009/1977 (W.176), S.I. 2009/1838 (W.166), S.I. 2011/1043, and S.I. 2012/1916.

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

- (a) in the entry for the drug Oseltamir (Tamiflu) for the entries in columns 2 and 3 respectively substitute—

"(1) 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) 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—

- (d) 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;
- (e) the patient has an influenza-like illness; and
- (f) the patient can start therapy within 48 hours of the onset of symptoms.

(2) 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.

Treatment of influenza

"(1) 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) 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—

- (d) 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;
- (e) the patient has an influenza-like illness; and
- (f) the patient can start therapy within 48 hours of the onset of symptoms.

(2) 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.

(3) 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—

Prophylaxis of influenza

- (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;
- (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.

(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) 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

(3) 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—

Prophylaxis of influenza

- (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;
- (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.

(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) 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.

(5) 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.”

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

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.

(5) 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.”

- (b) in the entry for the drugs for the treatment of erectile dysfunction, in column 2, after paragraph (f) insert—

“(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”.

“(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 cyffwr Zanamivir (Relenza), yn lle'r cofnodion yng ngholofnau 2 a 3, yn eu trefn, rhodder—

(a) in the entry for the drug Zanamivir (Relenza) for the entries in columns 2 and 3 respectively substitute—

“(1) 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—

Treatment of influenza

- (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

“(1) 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—

Treatment of influenza

- (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;
- (d) the patient has an influenza-like illness; and
 - (e) 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.

- was present at the time that the virus was circulating;
- (d) the patient has an influenza-like illness; and
 - (e) 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

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

Mark Drakeford

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol,
un o Weinidogion Cymru

Minister for Health and Social Services, one of the
Welsh Ministers

21 Mawrth 2013

21 March 2013

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Printed and Published in the UK by the Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

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