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WELSH STATUTORY INSTRUMENTS

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**2013 No. 683 (W.81)**

**NATIONAL HEALTH SERVICE, WALES**

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

<i>Made</i>	- - - -	<i>21 March 2013</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>22 March 2013</i>
<i>Coming into force</i>	- -	<i>12 April 2013</i>

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:

**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)—

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

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“(1) A patient who is aged 1 year 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

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(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.

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;

- (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) 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”.

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

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“(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”

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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21 March 2013

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

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

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.

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).

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.