

2009 No. 394

HEALTH AND PERSONAL SOCIAL SERVICES

**The Health and Personal Social Services (Prescribing and
Charging Amendments Relating to Pandemic Influenza)
Regulations (Northern Ireland) 2009**

Made - - - - *27th November 2009*

Coming into operation - *1st January 2010*

The Department of Health, Social Services and Public Safety(a) makes the following Regulations in exercise of the powers conferred by Articles 57D, 98 and 106(b) of, and Schedule 15 to, the Health and Personal Social Services (Northern Ireland) Order 1972(b) and with the approval of the Department of Finance and Personnel insofar as they relate to Charges for Drugs and Appliances.

Citation and commencement

1. These Regulations may be cited as the Health and Personal Social Services (Prescribing and Charging Amendments Relating to Pandemic Influenza) Regulations (Northern Ireland) 2009 and shall come into operation on 1st January 2010.

Amendment of the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997

2. After regulation 7 of the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997(c) insert the following regulation—

“Exemption from charges in respect of listed medicines

7A.—(1) No patient shall be liable to pay a charge under these Regulations in respect of the following medicines—

- (a) oseltamivir (marketed as Tamiflu);
 - (b) zanamivir (marketed as Relenza);
- in the circumstances set out in paragraph (2).

(2) Those circumstances are that—

- (a) the Department has made arrangements for supplying the medicine to patients free of charge; or

(a) See S.I. 1999/283 (N.I. 1) Article 3(6)

(b) S.I. 1972/1265 (N.I. 14) relevant amending instruments are S.I. 1986/2229 (N.I. 24); S.I. 1988/2249 (N.I. 24) Article 7; S.I. 1991/194 (N.I. 1) Part II of Schedule 5; 2001 c.3 (N.I.) section 48; S.I. 2004/311 (N.I. 2) Article 4; 2008 c. 2 (N.I.) section 14 and 2009 c.1 (N.I.) section 32 and Schedule 6

(c) S.R. 1997 No. 382 to which there are amendments not relevant to these regulations

- (b) the Regional Board that is responsible for the arrangements under which the medicine is supplied has made arrangements, with the approval of the Department for supplying the medicine to patients free of charge,
and the patient is supplied with the medicine under those arrangements.”.

Amendment of the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004

3. In Schedule 2 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004(a) (drugs, medicines and other substances to be ordered only in certain circumstances)—

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

“Oseltamivir (Tamiflu)	<p>(1) At-risk adult and child patients where —</p> <ul style="list-style-type: none"> (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. 	Treatment of influenza
	<p>(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 Department or are part the Regional Board’s antivirals distribution service.</p>	
	<p>(3) At-risk patients aged 13 years and older where —</p> <ul style="list-style-type: none"> (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; (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 — <ul style="list-style-type: none"> (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 	

(a) S.R. 2004 No.142

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) 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 Department or are part the Regional Board's antivirals distribution service.

”

; and

“Zanamivir
(Relenza)

(1) At-risk adult 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;
- (b) the patient has an influenza-like illness; and
- (c) the patient can start therapy within 48 hours of the onset of symptoms.

Treatment
of influenza

(2) 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 Department or are part the Regional Board's antivirals distribution service.

Prophylaxis
or treatment
of
influenza.

”.

(d) After the words “in this Schedule— ” insert in the appropriate alphabetical place —

““at-risk” means an adult or child patient or a patient over the age of 13 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) are immunocompromised;
- (e) has diabetes mellitus; or
- (f) is aged 65 years or over;”;

““child” means any person under the age of 16;”;

““patient” has the same meaning as in the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004(a)”; and

““residential care home” and “nursing home” have the same meaning as in the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(a).”.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 27th November 2009

(L.S.)

Christine Jendoubi

A senior officer of the Department of Health, Social Services and Public Safety

The Department of Finance and Personnel approves the foregoing Regulations insofar as they relate to Charges for Drugs and Appliances.

Sealed with the Official Seal of the Department of Finance and Personnel on 27th November 2009

(L.S.)

Adrian Arbuthnot

A senior officer of the Department of Finance and Personnel

(a) S.I. 2003/431 (N.I. 9)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 (“the Charges Regulations”) and the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004 (“the Drugs Regulations”).

Regulation 2 inserts a new exemption into the Charges Regulations, the new regulation 7A, the effect of which is that two named antiviral medicines will be exempt from the charging arrangements in the Charges Regulations, if distributed under arrangements for their free supply made by the Department of Health, Social Services and Public Safety (“the Department”) or the Regional Board.

Regulation 3 amends Schedule 2 of the Drugs Regulations in relation to the same two antiviral medicines to widen the circumstances under which they may be ordered for patients under general medical services contracts. Essentially, they may be ordered during outbreaks of pandemic influenza for treatment or prophylaxis of influenza, where this is under arrangements for the distribution of the medicines free of charge which are approved by the Department or the Regional Board.

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