2010 No. 2389

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2010

Made----28th September 2010Laid before Parliament4th October 2010Coming into force--1st November 2010

The Secretary of State for Health makes these Regulations in exercise of powers conferred by sections 88 and 272(7) and (8) of the National Health Service Act 2006(a).

Citation, commencement and application

- 1.—(1) These Regulations may be cited as the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2010 and come into force on 1st November 2010.
 - (2) These Regulations apply in relation to England.

Amendment to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

- **2.**—(1) Schedule 2 (drugs, medicines and other substances that may be ordered only in certain circumstances) to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004(**b**) is amended as follows.
 - (2) For the entry for "Oseltamivir (Tamiflu)" which is referred to in column 1—
 - (a) in the part which relates to "Treatment of influenza" (as mentioned in column 3), in column 2, in paragraph (1), from the words "At-risk adult" to the end of sub-paragraph (a), substitute—
 - "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 Department of Health has notified general medical practitioners that the influenza virus is circulating in the community(c);"; and
 - (b) in the part which relates to "Prophylaxis of influenza" (as mentioned in column 3), in column 2, in paragraph (2), from the words "At-risk patients" to the end of sub-paragraph (a), substitute—

⁽a) 2006 c.41. See section 275(1) for the definition of "prescribed" and "regulations".

⁽b) S.I. 2004/629; amending instruments are S.I. 2004/3215 and 2009/2230.

⁽c) Notification is given via the Central Alerting System, a web-based system used for distributing information relating to such matters as safety alerts, drug alerts and emergency alerts to general medical practitioners as well as other professionals in or connected with the health service. In addition, the notification is placed on the Department of Health's website which is www.dh.gov.uk.

- "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 Department of Health has notified general medical practitioners that the influenza virus is circulating in the community;".
- (3) For the entry for "Zanamivir (Relenza)" which is referred to in column 1, in the part which relates to "Treatment of influenza" (as mentioned in column 3), in column 2, in paragraph (1)—
 - (a) from the words "At-risk adult" to the end of sub-paragraph (a), substitute—
 - "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, where-
 - (a) the Department of Health has notified general medical practitioners that the influenza virus is circulating in the community;"; and
 - (b) for sub-paragraph (c) substitute—
 - "(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; and
 - (ii) who is aged 13 years or over, that patient can start therapy within 48 hours of the onset of symptoms.".
 - (4) At the end of the Table, in the interpretation provision—
 - (a) omit the definitions of "at-risk" and "child"; and
 - (b) in the appropriate alphabetical order, insert—

""at clinical risk" means in relation to a patient, a patient who—

- (a) has chronic respiratory disease;
- (b) has asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission;
- (c) has chronic heart disease;
- (d) has chronic renal failure;
- (e) has chronic liver disease;
- (f) has chronic neurological disease;
- (g) has diabetes; or
- (h) is immunosuppressed;" and

""general medical practitioner" has the same meaning as in the National Health Services (General Medical Services Contracts) Regulations 2004(a);".

Signed by authority of the Secretary of State for Health.

Earl Howe

28th September 2010

Parliamentary Under-Secretary of State, Department of Health

⁽a) S.I. 2004/291; relevant amending instrument is S.I. 2010/234.

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.) Regulations 2004 (S.I. 2004/629).

Regulation 2 amends Schedule 2 so the description of persons in respect of which Oseltamivir and Zanamivir may be ordered is widened and also to clarify the description of patients for whom both drugs may be ordered. The description of patients is widened so as to include pregnant patients and is also widened so those patients at clinical risk include those who have chronic liver disease and chronic neurological disease. The conditions which have to be met before both drugs are ordered are also amended. Oseltamivir may be ordered for patients who are aged 1 year and older who are at clinical risk. In the case of Zanamivir, that drug may be ordered for patients aged 5 years or over who are at clinical risk. In the case of a patient who has attained the age of 5 years but not the age of 13 years, Zanamivir may only be ordered if therapy can start within 36 hours of the onset of symptoms and in the case of patients aged 13 years or over, therapy can start within 48 hours.

A full impact assessment has not been produced for the instrument as no impact on the private or voluntary sector is foreseen.

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