

2011 No. 327

HEALTH AND PERSONAL SOCIAL SERVICES

The Health and Personal Social Services (General Medical Services Contracts)(Prescription of Drugs Etc) (Amendment) Regulations (Northern Ireland) 2011

Made - - - - *22nd September 2011*

Coming into operation - *13th October 2011*

The Department of Health, Social Services and Public Safety, in exercise of the powers conferred by Articles 57D and 106(b) of the Health and Personal Social Services (Northern Ireland) Order 1972(a), makes the following Regulations.

Citation and Commencement

1. These Regulations may be cited as the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) (Amendment) Regulations (Northern Ireland) 2011 and shall come into operation on 13th October 2011.

Substitution of new Schedule 2 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004

2. For Schedule 2 (drugs, medicines and other substances to be ordered only in certain circumstances) to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations 2004(b) substitute Schedule 2 as set out in the Schedule to these Regulations.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 22nd September 2011

(L.S.)

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

(a) S.I. 1972/1265 (N.I. 14) ; Article 57D was inserted by Article 4 of S.I. 2004/311 (N.I. 2)
(b) S.R. 2004 No. 142; amended by S.R. 2009 No. 394 and S.R. 2010 No. 375

SCHEDULE

Regulation 2

SCHEDULE 2 TO THE HEALTH AND PERSONAL SOCIAL SERVICES (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC) REGULATIONS (NORTHERN IRELAND 2004 AS SUBSTITUTED BY THESE REGULATIONS

“SCHEDULE 2

Regulation 3

DRUGS, MEDICINES AND OTHER SUBSTANCES TO BE ORDERED ONLY IN CERTAIN CIRCUMSTANCES

<i>Column 1 Drug</i>	<i>Column 2 Patient</i>	<i>Column 3 Condition</i>
Clobazam	Any patient	Treatment of epilepsy
Cyanocobalamin Tablets	A patient who is a vegan or who has a proven vitamin B12 deficiency of dietary origin	Treatment or prevention of vitamin B12 deficiency
Niferex Elixir 30ml Paediatric Dropper Bottle	Infants born prematurely	Prophylaxis and treatment of iron deficiency
Nizoral Cream	Any patient	Treatment of seborrhoeic dermatitis and pityriasis versicolor
The following drugs for the treatment of erectile dysfunction – Alprostadil (Caverject), (MUSE), (Viridal) Apomorphine Hydrochloride (Uprima) Moxisylyte Hydrochloride (Erecnos) Sildenafil (Viagra) Tadalafil (Cialis) Thymoxamine Hydrochloride (Erecnos) Vardenafil (Levitra)	(a) Any man with erectile dysfunction who on 14th September 1998 was receiving a course of treatment under the Order, the National Health Service Act 1977(a), or the National Health Service (Scotland) Act 1978(b) for this condition with any of the following drugs –Alprostadil (Caverject), (Muse), (Viridial) Apmorphine hydrochloride (Uprima) Moxisylyte Hydrochloride (Uprima) Moxisylyte Hydrochloride (Erecnos) Sildenafil (Viagra) Tadalafil (Cialis) Thymoxamine Hydrochloride (Erecnos) Vardenafil (Levitra); or (b) a man who is a national of an EEA State who is entitled to	Treatment of erectile dysfunction

(a) 1977 c. 49

(b) 1978 c. 29

	<p>treatment by virtue of Article 7(2) of Council Regulation 1612/68(a) as extended by the EEA Agreement or by virtue of any other enforceable Community right who has erectile dysfunction and was on 14th September 1998 receiving a course of treatment under a national health insurance system of an EEA State for this condition with any of the drugs listed in sub-paragraph (a); or</p> <p>(c) a man who is not a national of an EEA State but who is the member of the family of such a national who has an enforceable Community right to be treated no less favourably than the national in the provision of medical treatment and has erectile dysfunction and was being treated for that condition on 14th September 1998 with any of the drugs listed in sub-paragraph (a); or</p> <p>(d) a man who is suffering from any of the following –diabetes, multiple sclerosis, Parkinson’s disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida, spinal cord injury; or</p> <p>(e) a man who is receiving treatment for renal failure by dialysis; or</p> <p>(f) a man who has had the following surgery–prostatectomy; radical pelvic surgery; renal failure treated by transplant;</p>	
Oseltamivir (Tamiflu)	<p>(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 from influenza where—</p> <p>(a) the Department has notified general medical practitioners that the influenza virus is circulating in the</p>	Treatment of influenza

(a) O.J. No. L257, 19.10.68. p. 22 (O.J./S.E. 1968 (II) p. 475)

	<p>community(a);</p> <p>(b) the patient has an influenza-like illness; and</p> <p>(c) the patient can start therapy within 48 hours of the onset of symptoms.</p> <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) 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—</p> <p>(a) the Department has notified general medical practitioners that the influenza virus is circulating in the community;</p> <p>(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;</p> <p>(c) the patient is not effectively protected by vaccination against influenza because —</p> <p>(i) he has not been vaccinated because vaccination is contraindicated;</p> <p>(ii) he has not been vaccinated since the previous influenza season;</p> <p>(iii) he has been vaccinated but it has yet to take effect; or</p>	<p>Prophylaxis of influenza</p>
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(a) Notification is given by the Department of Health, Social Services and Public Safety via a letter from the Chief Medical Officer to general practitioners and other health professionals in or connected to the Health Service. In addition the notification is placed on the DHSSPS website which is www.dhsspsni.gov.uk

	<p>(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;</p> <p>(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</p> <p>(e) the patient can start prophylaxis within 48 hours of exposure to an influenza-like illness.</p> <p>(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.</p>	
Zanamivir (Relenza)	<p>(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—</p> <p>(a) the Department has notified general medical practitioners that the influenza virus is circulating in the community;</p> <p>(b) the patient has an influenza-like illness; and</p> <p>(c) in the case of a patient—</p> <p>(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</p> <p>(ii) who is aged 13 years or over, that patient can start therapy within 48 hours of the onset of symptoms.</p>	Treatment of influenza

<p>(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.</p>	<p>Prophylaxis or treatment of influenza.</p>
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In this Schedule—

“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;

“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993;

“EEA State” means a State which is a contracting party to the EEA Agreement;

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

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

“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(b).”

(a) S.R. 2004 No. 140 to which there are amendments not relevant to these Regulations

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations 2004 by substituting a new Schedule 2 to the Regulations.

The main changes to Schedule 2 are the widening of the description of persons in respect of which Oseltamivir and Zanamivir may be ordered to include those who are under 65 years of age, who are not pregnant, nor considered to be at clinical risk, but who are considered to be at risk of developing complications from the symptoms of influenza.

The Schedule also removes certain drugs, medicines and other substances which are no longer required to be listed (Locavbiotal Aerosol) and those drugs which were previously listed as being able to be prescribed where contact lenses were indicated for a therapeutic reason. Earlier typographical errors are also amended.

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STATUTORY RULES OF NORTHERN IRELAND

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