

Carwyn Jones AM/AC

Y Cwnsler Cyffredinol ac Arweinydd y T.
Counsel General and Leader of the House



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

Lord Dafydd Elis – Thomas AM
Presiding Officer
National Assembly Wales

21 July 2009

Dear Dafydd

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) (Amendment) (No.2) Regulations 2009

I am writing to inform you that in order to bring The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) (Amendment) (No.2) Regulations 2009 into force in Wales, it has become necessary to breach the 21 day rule. These Regulations were made on 20 July 2009, came into force on 21 July 2009 and were laid in Table Office on 21 July 2009.

These Regulations apply to the supply of antiviral drugs where there is a pandemic or anticipated pandemic disease. They amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) Regulations 2004 and apply to antiviral drugs which are currently listed in Schedule 2 to the 2004 Regulations, (drugs or medicines to be ordered only in certain circumstances) ("the Grey List"). Regulation 3 of the 2004 Regulations provides that the drugs listed in Schedule 2 may not be ordered for patients in the provision of general medical services under a GMS contract unless the patient is within the class and for the purposes defined in the Schedule. Accordingly, to ensure that GPs are able to issue prescriptions (WP10) for the anti-viral drug Zanamavir (Relenza) (as well as Oseltamivir (Tamiflu) for which previous amending Regulations have recently been made) in accordance with their GMS contractual obligations, a further amendment will need to be made to the 2004 Regulations to add further circumstances in which the drug Zanamavir (Relenza) may be ordered under a GMS contract to include-

- in the event that a disease is pandemic or in anticipation of a disease being imminently pandemic and;
- is a serious risk, or potentially a serious risk to human health;

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1NA

Ffôn • Tel 029 2082 8055
Ffacs • Fax 029 2089 8475
Correspondence.Carwyn.Jones@Wales.gsi.gov.uk

Wedi'i argraffu ar bapur wedi'i ailgylchu (100%)

Printed on 100% recycled paper

- and the supply of the drugs is in accordance with a protocol relating to that disease as provided for in article 12F of the Prescription Only Medicines (Human Use) Order 1997 or article 8 of the Medicines (Pharmacy and General Sale – Exemption) Order 1980.

The Regulations are required to come into force immediately to ensure that GPs are able to issue prescriptions for the anti-viral drug Zanamavir (Relenza) in accordance with their GMS contractual obligations. For these reasons it is considered necessary to breach the 21 day rule in order that the Regulations can come into force on 21 July 2009. Not making the legislation in Wales urgently would compromise our efforts to engage primary care services for an interim period in Wales whilst we continue to have a very low incidence of infection and that access to antiviral treatment for symptomatic individuals is made available through community pharmacy on prescription. This may lead to accusations of compromised public health safeguards in Wales during the pandemic.

Discussions have taken place with Community Pharmacy Wales (CPW), the Royal Pharmaceutical Society Great Britain (RPSGB) and the National Public Health Service (NPHS), who are fully supportive of this approach in the current circumstances.

Due to the immediacy of the Instrument, these Regulations have not been subject to a Regulatory Impact Assessment. However, an Explanatory Memorandum has been prepared and this has been laid, together with the Regulations, in Table Office.

A copy of this letter goes to Janet Ryder, Chair of the Subordinate Legislation Committee and to Bethan Davies, Clerk to the Subordinate Legislation Committee.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Caryl Jones', is written in a cursive style.