

## **Explanatory Memorandum to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) (Amendment) (No.2) Regulations 2009**

This Explanatory Memorandum has been prepared by the Health and Social Services Directorate General and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

### **Description**

These Regulations make changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) Regulations 2004 ("the 2004 Regulations").

### **Matters of special interest to the Subordinate Legislation Committee**

It is intended to engage primary care services for an interim period in Wales whilst there continues to be very low incidence of infection and that access to antiviral treatment for symptomatic individuals is made available through Community Pharmacy on prescription from the stockpile of antiviral medication held in Wales.

The Regulations are required to come into force immediately. In order for work to proceed with the minimum of delay it is considered necessary to breach the convention that they should be laid before the Assembly for 21 days before coming into force. The Counsel General and Leader of the House has written to the Presiding Officer notifying him of the breach.

### **Legislative Background**

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) (Amendment) Regulations 2009 are made by the Welsh Ministers in exercise of the powers conferred by sections 46 and 203(9) and (10) of the National Health Service (Wales) Act 2006. This instrument follows the negative resolution procedure.

### **Purpose and intended effect of the legislation**

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc) (Wales) (Amendment) (No. 2) Regulations 2009 further amend the 2004 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. 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 Zanamivir (Relenza) in accordance with their GMS contractual obligations, an amendment to Schedule 2 will be required to add further circumstances in which the drug Zanamivir (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;

- 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.

### **Implementation**

The risk of not implementing the legislation at this time 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.

### **Consultation**

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.

### **Regulatory Impact Assessment**

A Regulatory Impact Assessment has not been prepared for this instrument due to the tight timeframe and given that key stakeholders mentioned above are fully supportive of this approach.