

## **EXPLANATORY MEMORANDUM TO**

### **The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) (Amendment) Regulations (Northern Ireland) 2010**

**SR 2010 No. 375**

#### **1. Introduction**

- 1.1. This Explanatory Memorandum has been prepared by the Department of Health, Social Services and Public Safety to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The Statutory Rule is made under powers conferred on the Department by the Health and Personal Social Services (Northern Ireland) Order 1972 and is subject to the negative resolution procedure.

#### **2. Purpose**

- 2.1. These Regulations further amend the Health and Personal Social Services (General Medical Services Contracts)(Prescription of Drugs Etc) Regulations (NI) 2004 . 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.
- 2.2. 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.

#### **3. Background**

- 3.1. The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (NI) 2004 contain a list of drugs, medicines and other substances to be ordered only in certain circumstances. This list (Schedule 2 of the Regulations) was amended last year to widen the circumstances when two antiviral medicines (oseltamivir (Tamiflu) and zanamavir (Relenza)) could be ordered for “at risk” patients under general medical services contracts during an outbreak of pandemic influenza. The Department now needs to amend the list again to keep in line with recent Department of Health amendments. Based on expert advice, the Department of Health has widened the categories of “at risk” groups to include all pregnant women and patients who have chronic liver disease and chronic neurological disease. The conditions which have to be met before both drugs are ordered are also to be amended.

- 3.2. So that prescribers can start prescribing to the new categories when national surveillance schemes have indicated that the influenza virus is circulating in Northern Ireland the amending legislation needs to be in place as a matter of urgency. Prescribers would be in breach of their contractual terms of service if they prescribed outside the confines of Schedule 2.

#### **4. Consultation**

- 4.1. The Department of Health conducted a four week specific engagement exercise with the manufacturers of Tamiflu and Relenza – GlaxoSmithKline and Roche - and with the British Medical Association to seek their views on the proposed amendments. All of the consultees indicated that they were content with the proposals and raised no specific concerns.
- 4.2. In the interests of expediency the Department did not carry out a consultation with the BMA in Northern Ireland. However, they have been informed of these changes.

#### **5. Equality Impact**

- 5.1. As the measure has no adverse impact on section 75 groups the Department has concluded it is not necessary to submit this measure to a full EQIA.

#### **6. Regulatory Impact**

- 6.1. A Regulatory Impact Assessment is not considered necessary as there will be no adverse impact on business, charities, social enterprise or voluntary bodies.

#### **7. Financial Implications**

- 7.1. There are minimal financial implications in terms of additional cost.

#### **8. Section 24 of the Northern Ireland Act 1998**

- 8.1. The proposed legislation is considered compatible with section 24 of the Northern Ireland Act 1998. A copy of this letter will be sent to the Northern Ireland Human Rights Commission.

#### **9. EU Implications**

- 9.1. Not applicable

#### **10. Parity or Replicatory Measure**

- 10.1. Similar legislation has already been made by the Department of Health.

#### **11. Additional Information**

- 11.1. In order to have the Regulations operational as soon as possible the Department has not complied with the normal requirement to have 21 days between the making and operational dates.