EXPLANATORY MEMORANDUM TO

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

SR 2011 No. 327

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 ("the 2011 Regulations") amend the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations 2004 ("the 2004 Regulations") by substituting a new Schedule 2 to the Regulations.

2.2. 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 medical complications from the symptoms of influenza. Without these amendments, general medical practitioners would be in breach of their contractual terms of services if the drugs were ordered for those patients who are not included in the description in column 2 of Schedule 2.

2.3. 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.

3. Background

3.1. Regulation 3 of the 2004 Regulations provides that a general medical practitioner under the terms of their general medical services contract may not order specified drugs, medicines and other substances which are listed in column 1 of Schedule 2 to those Regulations unless a patient falls within a specified description and the drug, medicine or other substance is prescribed for a specified purpose. Column 2 of Schedule 2 describes the patients and column 3 specifies the condition for which the drug, medicine or substance is prescribed.

3.2. Schedule 2 of the 2004 Regulations was amended in 2009 and again in 2010 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. The Department is taking this opportunity to consolidate these and earlier changes by substituting a new Schedule 2 to the Regulations. Recently identified anomalies and typographical errors are also being remedied.

3.3. Based on expert advice, the Department of Health has widened the categories of "at risk" groups to include those aged under 65 and are at risk of developing medical complications from influenza. The main policy objective of the 2011 Regulations is to ensure that patients who are at risk of contracting influenza, who are considered likely to benefit from treatment with Tamiflu or Relenza if they become ill with influenza, can receive these treatments on the Health Service in certain circumstances. People who do not fall within the described group can obtain private prescriptions for these treatments – but not on the Health Service.

3.4. Experience from the influenza season in 2010/11 has shown that some people who are not in any of the current "at risk" categories and who have no particular or identifiable underlying conditions have become seriously ill with influenza. It is not possible to define this category of patient as anything other than "at risk of developing medical complications" if they become ill with the virus as the conditions which must be met before the drugs are prescribed will change in response to changing expert advice on the particular pathology of each outbreak of the virus. Prescribing decisions will therefore be informed by guidance communicated to GPs by the Chief Medical Officer, which itself may fluctuate depending on circumstances.

3.5. The 2011 amendment Regulations are required to ensure that general medical practitioners may order the two drugs for patients in a new category of patient "at risk of developing medical complications" without breaching their contractual terms of service.

3.6. The substituted Schedule also contains further unrelated changes. It 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.

4. Consultation

4.1. The Department conducted a targeted consultation with the manufacturers of Tamiflu and Relenza (GlaxoSmithKline and Roche), the British Medical Association (NI Committee), the General Practitioners' Committee of British Medical Association (NI) and Community Pharmacy NI (formerly the Pharmaceutical Contractors Committee) to seek their views on the proposed amendments. Responses received were generally supportive.

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. The Northern Ireland Human Rights Commission has already been advised of this legislation.

9. EU Implications

9.1. Not applicable

10. Parity or Replicatory Measure

10.1. The main amendments parallel changes elsewhere in the UK.

11. Additional Information

11.1. Not applicable.