

EXPLANATORY MEMORANDUM TO

The Health and Personal Social Services (Prescribing and Charging Amendments Relating to Pandemic Influenza) Regulations (Northern Ireland) 2009

SR No.- 394

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 by Articles 57D, 98, and 106 of, and Schedule 15 to, the Health and Personal Social Services (Northern Ireland) Order 1972, and with the approval of the Department of Finance and Personnel insofar as they relate to Charges for Drugs and Appliances, and is subject to the negative resolution procedure.

2. Purpose

- 2.1. These Regulations further amend the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 (“the Charges Regulations”) and the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations (Northern Ireland) 2004 (“the Drugs Regulations”).
- 2.2. Regulation 2 inserts a new exemption into the Charges Regulations, the new regulation 7A, the effect of which is that two named antiviral medicines will be exempt from the charging arrangements in the Charges Regulations, if distributed under arrangements for their free supply made by the Department of Health, Social Services and Public Safety (“the Department”) or the Regional Board.
- 2.3. Regulation 3 amends Schedule 2 of the Drugs Regulations in relation to the same two antiviral medicines to take account of an earlier omission and to widen the circumstances under which they may be ordered for patients under general medical services contracts. Essentially, they may be ordered during outbreaks of pandemic influenza for treatment or prophylaxis of influenza, where this is under arrangements for the distribution of the medicines free of charge which are approved by the Department or the Regional Board.

3. Background

- 3.1. Due to the current flu pandemic the Department needs to make technical changes to certain Regulations covering the prescribing of and charging for medicines. They are the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 and the HPSS (General Medical Services Contracts)(Prescription of Drugs, etc) Regulations (Northern Ireland) 2004.
- 3.2. The Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 set the charging regime for drugs and appliances in Northern Ireland.

They have already been amended in May 2009 to ensure that medicines supplied by the Board or a Trust under an antiviral protocol were supplied free of charge during a pandemic (or the threat of one). This anticipated a situation where such medicines were supplied directly to the public using an antiviral protocol rather than (as is currently the case) by a pharmacist on presentation of a GP's prescription. It is now proposed to further amend the Regulations to exempt oseltamivir (Tamiflu) and zanamavir (Relenza) from charge regardless of how they are supplied. This will bring the legislation up to date with the current distribution system where all Health Service supplies of these medicines are free of charge. The Department of Health made similar changes at the end of August 2009. These interim changes to the Northern Ireland legislation are needed to cover the period up to 1 April 2010 when all prescription charges will be abolished.

- 3.3. The HPSS (General Medical Services Contracts)(Prescription of Drugs, etc) Regulations (Northern Ireland) 2004 limit the prescribing of certain drugs, medicines or other substances under a general medical services contract. The Regulations contain two schedules. Schedule 1 lists the drugs, medicines and other substances that may not be prescribed under any circumstances. Schedule 2 specifies those that may be ordered in limited circumstances. Schedules 1 and 2 are replicated in the Northern Ireland Drug Tariff which provides guidance on the dispensing of prescriptions as well as details on fees and reimbursement.
- 3.4. The Department of Health recently amended their equivalent legislation to ease the restrictions on ordering two Schedule 2 drugs, oseltamivir and zanamivir, during pandemic flu. Schedule 2 of the Drugs Regulations is now amended in relation to the same two antiviral medicines to take account of an earlier omission and to widen the circumstances under which they may be ordered for patients under general medical services contracts. Essentially, they may be ordered during outbreaks of pandemic influenza for treatment or prophylaxis of influenza, where this is under arrangements for the distribution of the medicines free of charge which are approved by the Department or the Regional Board.

4. Consultation

- 4.1. No specific consultation has been conducted in NI. It was not considered appropriate for these amendments as the policy decisions (free distribution and the easement on prescribing restrictions during a pandemic) were already in operation due to the urgency of the pandemic situation. Consultation would have added an additional delay to the existing discrepancy between law and practice which the Department wished to rectify as soon as possible. In addition it is already public knowledge that charges for all prescriptions are due to end on 1 April 2010.

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 the impact of the reductions will not have an adverse impact on business, charities, social enterprise or voluntary bodies.

7. Financial Implications

- 7.1. There are minimal financial implications in relation to prescriptions as all prescription charges are to be abolished on 1 April 2010.

8. Section 24 of the Northern Ireland Act 1998

- 8.1. The proposed legislation is compatible with section 24 of the Northern Ireland Act 1998.

9. EU Implications

- 9.1. Not applicable.

10. Parity or Replicatory Measure

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

11. Additional Information

- 11.1. Not applicable.