EXPLANATORY MEMORANDUM TO

The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) (Amendment) Regulations (Northern Ireland) 2014

SR 2014 No. 215

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 the Health and Personal Social Services (Northern Ireland) Order and is subject to the negative resolution procedure.

2. Purpose

2.1. These Regulations ("the 2014 Regulations") amend Schedule 2 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs) Regulations (Northern Ireland) 2004 ("the 2004 Regulations"). Schedule 2 lists drugs, medicines and other substances that can only be prescribed to patients under a General Medical Services contract in certain circumsatncees. Schedule 2 is amended to clarify that drugs which may be ordered for the treatment of erectile dysfunction (ED) may also be ordered to treat other medical condition, other than ED, if it is considered appropriate. References to the brand names of the specified ED drugs have been omitted to clarify that the specified restrictions apply to all formulations of the active ingredient in whatever way they are presented. Additionally, entries relating to certain drugs have been omitted as these products are either no longer in patent or licensed for the treatment of erectile dysfunction.

2.2. Schedule 2 is also amended to remove the entry for Cyanocobalamin tablets ending the current restrictions on Vitamin B12 deficiency treatments.

3. Background

3.1. Schedule 2 to the 2004 Regulations currently restrict Health Service prescribing of drugs for the treatment of ED to patients with specified medical conditions (e.g. diabetes). Since the Regulations were originally introduced, some of the ED drugs listed in Schedule 2 have received licenses for the treatment of alternative medical conditions beyond those specified in Schedule 2. The 2014 Regulations amend Schedule 2 to clarify that any drug listed may also be ordered for any patient requiring treatment (other than ED) if the drug is considered appropriate for that condition. Without these amendments GPs would technically be acting in breach of their contractual terms. In addition, the 2014 Regulations remove references in Schedule 2 to brand names to make it clear that the ED prescribing restrictions apply to all formulations of the active ingredient in ED treatments. Certain ED treatments are licensed for different medical conditions (for example for the treatment of pulmonary arterial

hypertension (PAH) but under different brand names not listed in Schedule 2. It is believed that historically prescribers have prescribed these treatments under the PAH brand names for ED patients not meeting the medical restrictions in Schedule 2. By removing references to the brand names of the specified ED drugs restrictions now apply to all formulations of the active ingredients in whatever way they are presented. Additionally, certain of the listed drugs are either no longer in patent or licensed for the treatment of erectile dysfunction.

3.2. Schedule 2 to the 2004 Regulations currently restricts the prescribing of Cyanocobalamin to those patients who are vegans or have a proven vitamin B12 deficiency of dietary origin. Clinical evidence has emerged that diabetic patients who are being treated with Metformin can become vitamin B12 deficient. Under the current Schedule 2 provisions such patients could not be prescribed Cyanocobalamin. The 2014 Regulations remove the restriction on prescribing Cyanocobalamin allowing it to be prescribed to all patients.

4. Consultation

4.1. The Department conducted a targeted ten week consultation with the Association of the British Pharmaceutical Industry, the British Generic Manufacturers Association, the British Medical Association (NI Committee), the Northern Ireland General Practitioners Committee, the Royal college of General Practitioners, Community Pharmacy Northern Ireland and the Patient Client Council. All those who responded indicated they were content with the proposed Regulations.

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 amendments parallel changes elsewhere in the UK

11. Additional Information

11.1. Not applicable.