EXPLANATORY MEMORANDUM TO

Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (NI) 2019

S.R 2019 No.186.

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Health 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 63(1) and(2), 64, 106(b) and 107(6) of the Health and Personal Social Services (Northern Ireland) Order 1972 ("the 1972 Order") and is subject to the negative resolution procedure.

2. Purpose

2.1. These Regulations amend the Pharmaceutical Services Regulations Northern Ireland 1997 ("the Pharmaceutical Services Regulations") which govern the arrangements for the provision of pharmaceutical services under the 1972 Order.

2.2. They make provision in relation to serious shortage protocols (SSPs) to allow the Department of Health to put in place alternative arrangements for supply, where a drug or appliance is ordered on health service prescription but there is, or may in the future be, a serious shortage of the drug or appliance.

3. Background

3.1. The Human Medicines (Amendment) Regulations 2019 made a number of amendments to the Human Medicines Regulations 2012 which is UK-wide in its territorial application. Amongst the amendments, there is provision for the sale or supply of prescription-only medicines by retail pharmacy businesses under a "serious shortage protocol" (SSP) where there is or may be a serious shortage of particular prescription-only medicines. These protocols would allow for substitution, in restricted circumstances, of a different strength, quantity or pharmaceutical form of a prescription only medicine, or a different prescription only medicine, to that ordered by the prescriber

3.2. As part of Health Service pharmaceutical services, pharmacies and dispensing doctors dispense a wide range of products including pharmacy medicines, medicines on general sale, other drugs (such as medical foods) and appliances. For that reason, the Department of Health believes that it is logical to apply a protocol approach to any product that might be supplied under Health Service pharmaceutical services.

3.3. In order to avoid pharmacists and dispensing doctors acting in breach of their Terms of Service and to enable them to be paid by the Health Service when supplying in accordance with an SSP rather than dispensing against the relevant prescription, their Terms of Service need to be amended.

3.4. This will be achieved through the Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (NI) 2019. These Regulations will make a number of amendments to Schedule 2 to the Pharmaceutical Services Regulations to change the Terms of Service for pharmacists and for dispensing doctors who provide pharmaceutical services.

3.5. A further amendment provides that products supplied under an SSP should show on the dispensing label that the product was supplied against SSP rather than the patient's usual prescription. The purpose of this provision is to support patient safety and help them know which of their medicines have been supplied under an SSP. If they need further advice, they can potentially access information specific to that SSP using the code. Furthermore, if the patient then returns to their GP with the supplied medicine, it will be clear to the GP that the supply was made under an SSP.

4. Consultation

4.1. In accordance with Article 63(3) of the Health and Personal Social Services (Northern Ireland) Order 1972, the Department of Health has consulted with such organisations as appear to it to be representative of the pharmaceutical profession. The Regulations have been subject to consultation with the Health and Social Care Board, Business Services Organisation, Community Pharmacy NI, the Royal College of General Practitioners NI and the BMA's NI General Practitioners Committee. Responses have been supportive of the provisions within the Regulations.

5. Equality Impact

5.1. The Department has concluded that the proposed amendments will not have a significant impact on equality of opportunity for any group referred to in section 75 of the Northern Ireland Act 1998 and a full Equality Impact Assessment has not been considered necessary.

6. Regulatory Impact

6.1. It is not anticipated that there will be any adverse impact on business, charities, social economy or voluntary bodies.

7. Financial Implications

7.1. There are no anticipated financial implications to the Department of Health although there may be implications for the wider Health Service.

8. Section 24 of the Northern Ireland Act 1998

8.1. These Regulations do not breach section 24 of the Northern Ireland Act 1998, as they are not incompatible with any of the Convention rights or community law, and they do not discriminate against a person on the grounds or religious belief or political opinion.

9. EU Implications

9.1. There are no anticipated EU implications as a result of these amendments.

10. Parity or Replicatory Measure

10.1. These regulations replicate amendments to Regulations which will be made by England, Wales and Scotland.

11. Additional Information

11.1. Not applicable.