EXPLANATORY MEMORANDUM TO

The Pharmaceutical Services (Amendment) Regulations (Northern Ireland) 2022

SR 2022 No. 31

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 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 ("the 2022 Regulations") further amend the Health and Personal Social Services Pharmaceutical Services Regulations (Northern Ireland) 1997 ("the Pharmaceutical Regulations"), which regulate the terms under which pharmaceutical services are provided under the 1972 Order.

2.2. Regulation 2 inserts new definitions of "authorisation", "paramedic independent prescriber" and "therapeutic radiographer independent prescriber" into regulation 2 of the Pharmaceutical Regulations. It also substitutes new definitions of "prescriber" and "relevant register" in this regulation and amends the definition of "supplementary prescriber" to include dietitians. Finally it inserts a new definition of "PTP" (pandemic treatment protocol) into this regulation which is part of new measures that are being introduced as part of the response to the coronavirus pandemic, related to which is the expansion of the national programme for immunisation against influenza

2.3. Regulation 3 amends Schedule 2 to the Pharmaceutical Regulations to make provision to allow chemists and dispensing doctors to supply in accordance with a "PTP", which allows for the supply, without a prescription, of prescription only medicines used for the prevention or treatment of diseases that are, or in anticipation of them being imminently, pandemic. There are also supplementary provisions related to this requirement dealing with matters such as dispensing.

3. Background

3.1. Changes to the UK wide Human Medicines Regulations 2012 created three new groups of prescribers. Registered therapeutic radiographers and registered paramedics will be able to independently prescribe medicines while registered dieticians will be able to enter into supplementary prescribing arrangements. Supplementary prescribing is an arrangement whereby, after diagnosis by an independent prescriber, the supplementary prescriber can prescribe medicines as part of the patient's agreed clinical management plan. These new prescribers will have to undergo appropriate training. Increasing the range of prescribers makes it easier for patients to

get the medicines they need, increases patient choice and makes better use of the skills of healthcare professionals.

3.2. Prescriptions issued by these three prescribers in secondary care can routinely be dispensed by hospital pharmacists.

3.3. However, amendments are required to the Pharmaceutical Regulations to make provision for a community pharmacist to dispense against a HS21 prescription that is written by either therapeutic radiographer independent prescribers, paramedic independent prescribers or dietitian supplementary prescribers in primary care.

3.4. Further amendments are made to the Pharmaceutical Regulations relating to the dispensing by chemists and dispensing doctors of medication against pandemic treatment proptocols as a result of the Human Medicines (Coronavirus and Influenza)(Amendment) Regulations 2020, to support the rapid and effective rollout of a COVID-19 vaccine and the influenza (flu) vaccine in the UK.

4. Consultation

4.1. The Department consulted with a number of health and social care organisations, as well as relevant representative and professional bodies in 2016 in relation to amending the Pharmaceutical Regulations to add therapeutic radiographer independent prescriber and dietician supplementary prescriber. Four consultation responses were received all of which were content with the proposed amendments.

4.2. As an amendment to the HMRs 2012 to add paramedic independent prescriber, had not been agreed by the Commission for Human Medicines (CHM) prior to the commencement of the department's 2016 consultation, paramedics were not part of that consultation. However the majority of respondents (over 90%) to the NHS England UK-wide consultation on independent prescribing supported the policy proposals for paramedics to become independent prescribers. Following agreement by the CHM, the HMRs 2012 were amended in 2018 to add paramedic independent prescriber.

4.3. In accordance with the 1972 Order, the Department also consulted in 2021on these Regulations with Community Pharmacy NI (the representative body for community pharmacies in NI), the Royal College of GPs (NI) and the BMA Committee for NI, which supported the amendments.

4.4. The proposed changes to the Human Medicines Regulations 2012 to support the rapid and effective rollout of a COVID-19 vaccine and the influenza (flu) vaccine in the UK, were the subject of a UK wide consultation.

5. Equality Impact

5.1. The Department of Health has conducted an Equality Impact Assessment screening exercise and has concluded that a full EQIA is not necessary.

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. Total costs of circa £547K are anticipated for training and governance arrangements for the additional non-medical prescribers (NMP) specified at Para 2.2 above. This figure inlcudes costs associated with the Health and Personal Social Services (General Medical Services Contracts) (Amendment) Regulations (Northern Ireland) 2022 which will also add these, and other prescribers, to The Health and Personal Social Services (General Medical Services Contract) (NI) Regulations 2004.

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.

9. EU Implications

9.1. Not applicable.

10. Parity or Replicatory Measure

10.1. The amendments relating to prescribing update the Pharmaceutical Regulations to reflect changes already made under the UK wide Human Medicines Regulations 2012.

11. Additional Information

11.1. Not applicable.