EXPLANATORY MEMORANDUM

The Misuse of Drugs (Amendment) Regulations (Northern Ireland No. 2) 2023

S.R. 2023 No. 218

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 sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 (the 1971 Act) as adapted by sections 7(9), 31(4) and 38 of that Act and now vested in it and after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 31(3) of that Act.

1.3 These Regulations are subject to negative resolution before the Northern Ireland Assembly.

2. Purpose of the Regulations

2.1 The purpose this Statutory Rule is to:

i. enable paramedic independent prescribers and therapeutic radiographer independent prescribers in Northern Ireland to prescribe and administer a limited number of controlled drugs;
ii. enable the supply of three codeine-based products by registered podiatrists; and
iii. make a number of technical amendments in relation to podiatrist independent prescribers, physiotherapist independent prescribers and healthcare professionals acting under patient group directions.

3. Background and Legislative Context

3.1 The Advisory Council on the Misuse of Drugs (ACMD) makes recommendations to Government on the control of dangerous or otherwise harmful drugs, including classification and scheduling under the Misuse of Drugs Act 1971 and its subsequent Misuse of Drugs Regulations. The medical use of Controlled Drugs is a devolved matter and permitted through the Misuse of Drugs Regulations (NI) 2002 ("the 2002 Regulations") and subsequent amendments. These Regulations define the classes of person who are authorised to possess and supply controlled drugs while acting in their professional capacity and lay down the conditions under which these activities may be carried out in Northern Ireland.

3.2 The UK Government consulted on proposals to enable prescribing of five specified controlled drugs by paramedic independent prescribers in 2015, which were then reviewed by the Commission on Human Medicines (CHM). Changes to the Human Medicines Regulations 2012 ("the 2012 HMRs) were then made to implement this policy.

3.3 The UK Government also consulted on proposals to enable prescribing of six specified controlled drugs by radiographers in 2015, which were then reviewed by the CHM. Changes to the 2012 HMRs were then made to implement this policy for therapeutic radiographer independent prescribers. As these proposals

related to controlled drugs, the ACMD provided advice on them, recommending that both proposals be implemented through amendments to the Misuse of Drugs Regulations in devolved administrations. The ACMD concluded that such proposals, subject to clinical and professional competence, would not increase the risk of diversion.

3.4 In addition, the ACMD also provided advice in 2022 recommending that the respective Misuse of Drugs Regulations complement the existing legislative framework set out in the 2012 HMRs to enable podiatrists to supply co-codamol, co-dydramol and codeine phosphate with necessary safeguards in place.

3.5 As the amendments to the Misuse of Drugs Regulations would take time, and in order to address this anomaly in the short term and avoid disruption to patient care, an interim solution was implemented for the UK via the issuing of Written Authorities, by the Home Office and Department of Health (NI) using existing powers in their respective Misuse of Drugs Regulations, to fill the immediate gap. The intention here was that these two Written Authorities would then be revoked once the respective Regulations were amended.

4. Consultation

4.1 The UK Government conducted two public consultations in 2015, one on proposals to introduce independent prescribing by paramedics and the other for independent prescribing by radiographers. The vast majority of respondents gave approval for the changes being implemented. To allow supply of the specified codeine-based products by podiatrists, the Royal College of Podiatrists were consulted prior to the introduction of the written authority issued in 2022.

4.2 These Regulations therefore amend the 2002 Regulations to complement the changes already made to the 2012 HMRs to give authorisation to paramedic independent prescribers to prescribe and administer the following controlled drugs: morphine sulphate; diazepam; midazolam; lorazepam; and codeine phosphate. They also give authorisation to therapeutic radiographer independent prescribers to prescribe and administer the following controlled drugs: tramadol; lorazepam; diazepam; morphine; oxycodone; and codeine.

5. Equality impact

5.1 The Department of Health 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 these Regulations will have any adverse impact on business, charities, social economy or voluntary bodies.

7. Financial implications

7.1 None anticipated.

8. Section 24 of the Northern Ireland Act 1998

8.1 The Department of Health has considered section 24 of the Northern Ireland Act 1998 and is satisfied that these Regulations are not incompatible with any of the Convention rights; are not incompatible with Community law; do not discriminate against a person or class of person on the grounds of religious belief or political opinion; and do not modify an enactment in breach of section 7 of the Northern Ireland Act 1998.

9. EU implications

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

10. Parity or Replicatory Measure

10.1 The provisions included in the Statutory Rule seek to replicate similar amendments to the Misuse of Drugs Regulations 2001 which are being taken forward by the Home Office and will ensure that the legislative arrangements in Northern Ireland will be in line with GB.

11. Additional information

11.1 Not applicable