EXPLANATORY MEMORANDUM TO

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2019

SR 2019 No. 21

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 sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 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 ('ACMD') in accordance with section 31(3) of that Act and is subject to the negative resolution procedure.

2. Purpose

2.1. The purpose of this instrument is to add pregabalin and gabapentin to Schedule 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002 ('the 2002 Regulations') and to the list of drugs in Schedule 1 to the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 ('the 1973 Regulations').

3. Background

3.1. The Misuse of Drugs Act 1971 (Amendment) Order 2018 ('the 2018 Order') controls gabapentin and pregabalin as Class C drugs under the Misuse of Drugs Act (‘the 1971 Act’) and comes into force on 1 April 2019. Amendments to the 2002 Regulations and the 1973 Regulations are necessary to complement the 2018 Order. As required by the 1971 Act, this instrument is made following consultation with the ACMD. The changes have been subject to a public consultation.

3.2. The 1971 Act controls drugs that are “dangerous or otherwise harmful”. Section 7(3) of the 1971 Act requires regulations to be made to allow drugs controlled under the Act to be used for medicinal purposes. The 2002 Regulations regulate the legitimate access to controlled drugs, and the Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2019 (‘the 2019 Regulations’) add pregabalin and gabapentin to Schedule 3 of those Regulations. The Schedule into which a drug is placed dictates primarily the extent to which it is lawful to import, export, produce, supply, administer and possess that drug, and also imposes requirements about prescription writing, record keeping, labelling and destruction. See paragraph 3.5 for further detail.

3.3. The 1973 Regulations provide for the safe custody of controlled drugs, and require such controlled drugs, other than those specified in Schedule 1, generally to be kept either in a locked safe or room or in a locked receptacle. The 2019 Regulations add pregabalin and gabapentin to

Schedule 1 to the 1973 Regulations as drugs which are exempted from the safe custody requirements of the 1973 Regulations. See paragraph 3.6 for further detail.

3.4. As the 2018 Order controls gabapentin and pregabalin as Class C drugs under the 1971 Act, these regulations are necessary to ensure their continued availability for legitimate use and to make provision in respect of safe custody.

3.5. Pregabalin and gabapentin are used to treat a variety of conditions, including epilepsy, postherapeutic neuralgia, diabetic peripheral neuropathy and fibromyalgia, and in the management of neuropathic pain. The ACMD recommended that these drugs be scheduled under Schedule 3 to the 2002 Regulations so as not to preclude legitimate use on prescription. Placing gabapentin and pregabalin under Schedule 3 ensures that these drugs will be accessible for medical needs, subject to measures of control. As Schedule 3 drugs, they will be subject to regulations 14 (documentation), 15 (form of prescriptions), 16 (supply on prescription), 22 to 24 (record-keeping and requirements as to registers and other documents), 26 (furnishing of information) and 27 (destruction of the drugs). Measures that they will be subject to include: the writing of prescriptions to specific requirements, including the wet signature of the prescriber, record keeping details about the quantity of the drugs, and the preservation of record keeping registers for two years.

3.6. As Schedule 3 drugs, pregabalin and gabapentin would ordinarily be subject to safe custody requirements. However, due to the large quantities prescribed and dispensed - and to reflect concerns raised, in responses to the consultation document, about the potential costs to store these in controlled drug safes - pregabalin and gabapentin are being exempted from these requirements. The drugs are therefore added to the list of drugs in Schedule 1 to the 1973 Regulations. This avoids any impact (such as additional costs to buy and install safes) from storage requirements on hospitals, pharmacies and businesses, etc.

4. Consultation

4.1. ACMD consulted a range of experts before providing advice. The Home Office and Department of Health (NI) jointly issued a UK wide ten week public consultation on the scheduling proposals in line with ACMD advice.

5. Equality Impact

5.1. Consideration has been given to compliance with section 75 of the Northern Ireland Act 1998 and the Department has concluded that specific impacts are likely to be minor. A full equality impact assessment was therefore not completed.

6. Regulatory Impact

6.1. The legislation applies to small businesses but the impact will be minimal. The harm that can be done through misuse and diversion of these drugs is such that it is anticipated all businesses will comply with the new legislative requirements.

7. Financial Implications

7.1. There are no anticipated financial implications to the Department of Health. However there will be costs to the Health and Social Care Board with regards to the dispensing fee for controlled drugs however it is believed this will be mitigated by a reduction in prescribing over time.

8. Section 24 of the Northern Ireland Act 1998

8.1. The Department is satisfied that this legislation is compliant with Section 24 of the Northern Ireland Act 1998

9. EU Implications

9.1. There are no anticipated EU implications.

10. Parity or Replicatory Measure

10.1. These regulations replicate amendments to the Misuse of Drugs Regulations 2001- which apply to England, Wales and Scotland.

11. Additional Information

11.1. Not applicable