EXPLANATORY MEMORANDUM TO

The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2020

SR 2020 No. 73

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 and is subject to the negative resolution procedure.

2. Purpose

2.1. The purpose of this statutory rule is to amend the Misuse of Drugs Regulations (Northern Ireland) 2002 ("the 2002 Regulations") to provide flexibility in an emergency situation, such as a pandemic, to relax rules on possession and supply to allow pharmacists in registered pharmacies to supply controlled drugs to patients, without a prescription, in two circumstances.

2.2. The circumstances as set out below, relate to arrangements with a person lawfully conducting a retail pharmacy business, to ease the normal restrictions on supplies of prescription only medicines (POMs), which are also controlled drugs, in the Human Medicines Regulations 2012 (HMRs), and relate essentially to continuity of treatment.

2.3. The first change will allow pharmacists, operating in a registered pharmacy premises, to supply controlled drugs to patients in the absence of a prescription. To permit the supply the patient must have previously been prescribed such drugs by an appropriate prescriber. Provisions are already in place for POM supplies in this manner.

2.4. The second relates to supplies under a Serious Shortage Protocol (SSP). Currently there is a mechanism to help manage a serious shortage (not necessarily in a pandemic situation), by which a pharmacist at a registered pharmacy may, under a SSP issued by the Secretary of State for Health and Social Care and the Minister for Health (NI) acting jointly or alone, supply an alternative quantity, strength, pharmaceutical form or medicine that is both available and suitable as prescribed in the protocol. This amendment will extend the SSP provision to include controlled drugs.

2.5. In addition these Regulations will permit a pharmacist to change the intervals on prescriptions for Schedule 2 and 3 drugs supplied to a patient in instalments, subject to agreement of the prescriber or, if the prescriber is unavailable, a member of the same team responsible for treating the patient, who has been designated as able to agree this type of change.

2.6. An announcement by the Department of Health will specify how any of the above arrangements will apply and the period they will apply. Any announcement will be particularly directed towards prescribers and community pharmacy contractors. The arrangements must not be for more than three months initially but may be extended for further periods of not more than three months at a time.

2.7. The amendments will help alleviate pressures on community pharmacies and GP Practices during emergency situations such as a pandemic.

3. Background

3.1. The 1971 Act controls drugs that are "dangerous or otherwise harmful" either to individuals or to society when they are misused. It lists all drugs subject to control in Schedule 2 to the Act in three categories; Classes A, B and C, according to their perceived degree of harm and applies maximum penalties to offences committed under the Act. Access to controlled drugs for legitimate medicinal purpose is permitted, but subject to regulation, through the 2002 Regulations. The 2002 Regulations establish a regime of control around prescribing, supplying or administering, safe custody, dispensing, record keeping, destruction and disposal. The single purpose of these restrictions is to prevent the diversion and misuse of controlled drugs for patient and public protection.

3.2. Section 5 of the 1971 Act places a general restriction on possessing controlled drugs, subject to exceptions in regulations. In the case of drugs dispensed and supplied by registered pharmacists, relevant exceptions for drugs specified in Schedules 2 to Part 1 of Schedule 4 presuppose the existence of directions of a person lawfully entitled to prescribe the drug.

3.3. A new regulation 10A is inserted into the 2002 Regulations which gives powers to the Department of Health to make an announcement in an emergency situation, such as a pandemic, that would permit pharmacists to supply at registered pharmacy premises, controlled drugs previously supplied to a patient on prescription. The HMRs already permit POMs to be supplied in a pandemic in the absence of a prescription and a pharmacist can also utilise a Serious Shortage Protocol (SSP). This amendment will allow controlled drugs to be included within the scope of these arrangements. In the absence of this amendment such supplies would be unlawful.

3.4. SSPs in relation to POMs were introduced in 2019. An SSP enables community pharmacists, in the event of a serious shortage of any prescribed item, to supply in accordance with the Protocol rather than against a prescription, without going back to the prescriber.

3.5. Controlled drugs are not permitted under SSPs by virtue of the Misuse of Drugs Regulations preventing the supply of Schedule 2, 3 and 4 (part 1) controlled drugs without a prescription. It should be noted that Part II of Schedule 4 and Schedule 5 substances are permitted under SSPs.

3.6. Regulation 10A (c) permits a pharmacist in a retail pharmacy business, under a SSP issued by the Secretary of State for Health and Social Care and the Minister for Health (NI) acting jointly or alone, to supply an

alternative quantity, strength, pharmaceutical form or medicine that is both available and suitable as prescribed in the protocol. This includes drugs specified in Schedule 2 to Part 1 of Schedule 4 (regulation 4) in the case of supplies for the provision of health services.

3.7. Opioid substitute treatment (OST) is the term used to describe the prescribing of an opioid medication to assist patients who are seeking treatment for dependent use of heroin or other opioids. Maintaining OST, with drugs such as methadone and buprenophine, during a pandemic/national emergency is critical. These drugs are normally supplied by instalments. Non-OST patients may also be presribed drugs in instalments, for example those with compliance problems.

3.8. Restrictions on the form of prescriptions of Schedules 1 to 3 drugs in the 2002 Regulations include, for drugs intended to be supplied by instalments, the requirement on the prescriber to specify the intervals between the supply of the instalments. Pharmacists are not currently able to vary dispensing from the instalment instructions without requesting a new prescription.

3.9. Regulation 15 of the 2002 Regulations is amended to give powers to the Department of Health in a pandemic and where there is a serious risk to human health, to make an announcement that would permit pharmacists to vary the frequency for Schedule 2 and 3 drugs. This is subject to the prescriber's agreement, or if the prescriber is unavailable, a member of the same team responsible for treating the patient, who has been designated as able to agree this type of change. For example, moving from dispensing three times a week to once a week intervals. The total quantity supplied would remain as specified on the prescription.

3.10. An announcement made by the Department of Health in any of the above circumstances is subject to the conditions at 2.6 above.

3.11. There is also a consequential amendment to the interpretation provision of the 2002 Regulations.

4. Consultation

4.1. The UK Government (Department of Health and Social Care (DHSC)) and the Home Office) urgently consulted with the Advisory Council on the Misuse of Drugs (ACMD) in the drafting of a Statutory Instrument to amend The Misuse of Drugs Regulations 2001 and the Misuse of Drugs Regulations (Northern Ireland) 2002. The proposed legislative changes are on the basis of the ACMD advice.

5. Equality Impact

5.1. The legislative changes are on the basis of advice from the ACMD. No adverse impact on any of the Section 75 groups has been identified.

6. Regulatory Impact

6.1. These amendments are made in response to an emergency situation and there will be some impact on community pharmacists who will be required to supply controlled drugs without a prescription in specified circumstances and potentially at a different frequency. However, as the

clients should be known to the pharmacy, the business impact is considered manageable and a manual system of reimbursement for these supplies has already been put in place with the Business Services Organisation.

7. Financial Implications

7.1. Funding is being made available to community pharmacy contractors for the delivery of an Emergency Supply Service, via a scheme put in place by the Health and Social Care Board in response to the Covid-19 pandemic which will allow repeat prescriptions to be dispensed under certain conditions. The proposed amendments would include controlled drugs within that 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 of 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. The provisions included in the Statutory Rule seek to replicate amendments to the Misuse of Drugs Regulations 2001 which are urgently being taken forward by 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.