EXPLANATORY MEMORANDUM TO

The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2019

SR 2019 No. 208

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 as adapted by section 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") in order to:

2.2. amend the generic definition of a range of synthetic cannabinoids controlled as Schedule 1 compounds under the 2002 Regulations to reduce the scope of the definition. (As a result, those compounds which were unintentionally captured will no longer require a licence for the conduct of research, as they will no longer be controlled);

2.3. amend the definition of a health prescription to include Health Service prescriptions issued by physiotherapitst independent prescribers and podiatrist independent prescribers;

2.4. include new definitions of "juvenile justice centre", "nursing home", "prison" and "organisation providing ambulance services", include specific provisions relating to juvenile justice centres and prisons and provide the Northern Ireland Ambulance Health and Social Care Trust with a similar authority to that currently applicable to hospitals and nursing homes to supply Schedule 2 to 5 controlled drugs;

2.5. introduce limited independent prescribing authorities for physiotherapist independent prescribers and podiatrist independent prescribers;

2.6. regularise the emergency supply of phenorbarbital or phenorbarbital sodium in the absence of a valid prescription, subject to certain conditions;

2.7. replace the expression "extended formulary nurse prescriber" with "nurse independent prescriber";

2.8. extend the authority to supply or offer to supply controlled drugs to the person in charge or acting person in charge of an organisation providing ambulance services, and to a registered midwife who for the time being is in charge of a ward, theatre or other department in the hospital, nursing home, in a juvenile justice centre or prison;

2.9. provide authority for the Northern Ireland Ambulance Health and Social Care Trust to supply Schedule 2 to 5 controlled drugs directly to their registered paramedics for use in the immediate treatment of sick or injured persons;

2.10. make the use of a specific form for the requisitioning of Schedule 2 and 3 controlled drugs mandatory;

2.11. include paramedics, operating department practitioners and registered midwives in the list of healthcare professionals requiring a requisition in order to obtain stocks of Schedule 2 and 3 controlled drugs;

2.12. exempt hospices, juvenile justice centres and prisons from the requirement to present requisitions when obtaining stocks of controlled drugs;

2.13. make it a requirement for veterinary practitioners to include their Royal College of Veterinary Surgeon number on prescriptions for Schedule 2 and 3 controlled drugs;

2.14. add an organisation providing ambulance services to those who are required to preserve and provide information relating to controlled drugs;

2.15. the expression "registered chiropodist" is replaced with "registered podiatrist".

3. Background

3.1. This statutory rule is made under sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 (“the 1971 Act”). 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 Misuse of Drugs Regulations (Northern Ireland) 2002 ("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. These Regulations amend Schedule 1 to the 2002 Regulations to reduce the range of compounds captured by one of the definitions of synthetic cannabinoids to which the Schedule applies (the controlled drugs listed in Schedule 1 are subject to the tightest controls).

3.3. Regulation 2(2) is amended by including within the definition of “health prescription” physiotherapist independent prescribers and podiatrist independent prescribers as persons who may issue such a prescription.

3.4. They also insert definitions of “juvenile justice centre”, “nursing home”, “organisation providing ambulance services”, “podiatrist independent prescriber”, “physiotherapist independent prescriber” and “prison” in regulation 2(2) of the 2002 Regulations.

3.5. Regulations 6 and 7 of the 2002 Regulations are amended to give limited prescribing powers for certain controlled drugs to physiotherapist independent prescribers and podiatrist independent prescribers. Regulation 6 is also amended to allow the emergency supply (or offer to supply) of phenobarbital or phenobarbital sodium by a person lawfully conducting a retail pharmacy business, subject to certain conditions. The expression "extended formulary nurse prescriber" is replaced with "nurse independent prescriber".

3.6. Regulation 8 of the 2002 Regulations is amended by including within paragraph (2), in relation to the supply or offer to supply any controlled drugs specified in Schedules 2 and 5 to the 2002 Regulations, in certain circumstances, by a person who is in charge, or is acting person in charge, of an organisation providing ambulance services, and by substituting a new paragraph (2)(e) which includes reference to the supply of such a drug in a juvenile justice centre or prison by a registered midwife, who for the time being is in charge of a ward, theatre or other department in the hospital, nursing home, juvenile justice centre or prison.

3.7. Regulation 9 of the 2002 Regulations is amended by including in paragraph (3), in relation to the supply or offer to supply any drug specified in Schedules 3 or 4 to the 2002 Regulations, by a person who is in charge, or is acting person in charge, of an organisation providing ambulance services.

3.8. Regulation 14 of the 2002 Regulations is amended by specifying that the form of requisition to be obtained by a supplier of controlled drugs is to be in the form approved by the Department of Health. It is also amended to allow a person who is in charge, or is acting person in charge, of an organisation providing ambulance services, an operating department practitioner and a person who holds a certificate of proficiency in ambulance paramedic skills are added to the list of recipients in regulation 14(4) of the 2002 Regulations. The requisition required under regulation 14(6) applying when a controlled drug is supplied, in any hospital, nursing home, to a senior registered nurse or acting senior registered nurse, is widened to include an operating department practitioner and a registered midwife and to include juvenile justice centres and prisons. A new paragraph (7)(d) is inserted into regulation 14 providing that nothing in that regulation shall have effect in relation to any drug which is required for use in a juvenile justice centre, prison or institution, which as its whole or main purpose provides palliative care, subject to the provisions of paragraph (6).

3.9. Paragraph 15(1)(d) is amended to require prescriptions issued by a veterinary surgeon or veterinary practitioner to include the registration number of the person issuing it.

3.10. Regulation 19(3) of the 2002 Regulations, in respect of those persons to whom the record-keeping requirements set out in that regulation do not have effect, is amended to include a registered midwife and to include juvenile justice centres and prisons within this exemption.

3.11. Regulations 24 and 26 of the 2002 Regulations, in relation to the preservation of records relating to drugs in Schedules 3 and 5 and the furnishing of information with respect to controlled drugs respectively, are amended to refer to a person who is in charge, or is acting person in charge, of an organisation providing ambulance services.

3.12. The expression "registered chiropodist" in paragraph 1(e) of Schedule 8, is replaced with "registered podiatrist".

3.13. The requirement to use a mandatory form for the requisitioning of Schedules 2 and 3 controlled drugs shall not, apply to requisitions issued before the coming into operation of these Regulations.

3.14. The amendment to Regulation 15(1)(d) which introduces a requirement to include a Royal College of Veterinary Surgeons registration number on a veterinary prescription for Schedules 2 and 3 controlled drugs, shall not apply to veterinary prescriptions issued before the coming into operation of these Regulations.

4. Consultation

4.1. The Department of Health conducted a public consultation in 2011 on proposals to consolidate and review specific provisions under the 2002 Regulations. The vast majority of respondents gave approval for the changes being implemented.

4.2. A UK wide consultation on physiotherapist and chiropodist/podiatrist independent prescribing was conducted separately. https://www.gov.uk/government/publications/prescribing-powers-proposed-for-physiotherapists-and-podiatrists.

4.3. A Department of Health stakeholder engagement exercise during August/September 2019 indicated positive support for the proposed amendments. Stakeholders were made aware that, following a recommendation from the Advisory Council on the Misuse of Drugs (ACMD) a further amendment relating to the generic definition of a range of ‘third generation’ synthetic cannabinoids, would be included in the final Regulations. The UK Government also consulted representatives from the research community in relation to this amendment.

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 there will be 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. 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 politicial 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 and will keep Northern Ireland in line with GB amendments.

11. Additional Information

11.1. Not applicable.