2019 No. 208

DANGEROUS DRUGS

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

Made	-	-	-	-	24th October 2019
Coming	into d	opera	ation	-	15th November 2019

The Department of Health(**a**) makes the following Regulations in exercise of the powers conferred by sections 7, 10, 22 and 31 of the Misuse of Drugs Act $1971(\mathbf{b})$ as adapted by sections 7(9), 31(4) and 38 of that Act and now vested in it(**c**) and after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 31(3) of that Act.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2019 and shall come into operation on 15th November 2019.

(2) The Interpretation Act (Northern Ireland) $1954(\mathbf{d})$ shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002

2. The Misuse of Drugs Regulations (Northern Ireland) 2002(**e**) are amended in accordance with regulations 3 to 17 below.

Amendment of Regulation 2

3. In regulation 2(2)—

- (a) in the definition of "health prescription" after "a pharmacist independent prescriber," insert "a physiotherapist independent prescriber, a podiatrist independent prescriber";
- (b) after the definition of "installation manager" insert—

""juvenile justice centre" has the same meaning as in Article 51(1) of the Criminal Justice (Children) (Northern Ireland) Order 1988(**f**);";

(c) after the definition of "nurse independent prescriber" insert—

(b) 1971 c. 38 as amended by section 151 of, and Schedule 17 to, the Police Reform and Social Responsibility Act 2011 c.13

⁽a) Formerly the Department of Health, Social Services and Public Safety; see 2016 c. 5 (N.I.), section 1(5)

⁽c) S.R. & O. (N.I.) 1973 No. 504, Article 5(a) and S.I. 1999/283 (N.I. 1), Article 3(6)

 $^{(\}textbf{d}) \quad 1954 \; c.\; 33 \; (N.I.)$

⁽e) S.R. 2002 No. 1. Relevant amending Regulations are S.R. 2019 No. 21, S.R. 2018 Nos. 173 and 4, S.R. 2016 No. 29, S.R. 2015 No. 227, S.R. 2015 No. 53, S.R. 2014 Nos 261, 158 and 21, S.R. 2013 Nos. 78, S.R. 2012 No. 213, S.R. 2011 No. 153, S.R. 2010 Nos. 247 and 148, S.R. 2009 No. 390, S.R. 2007 No. 348 and S.R. 2005 No. 360

⁽f) S.I. 1998/1504 (N.I. 9)

""nursing home" has the same meaning as in Article 11 of the Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003(**a**);";

(d) after the definition of "operating department practitioner" insert-

""organisation providing ambulance services" means the Northern Ireland Ambulance Service Health and Social Care Trust as established by the Northern Ireland Ambulance Service Health and Social Care Trust (Establishment) Order (Northern Ireland) 1995(**b**);";

(e) after the definition of "pharmacist independent prescriber" insert-

""physiotherapist independent prescriber" has the same meaning as in the Human Medicines Regulations 2012(c), and such a person may only prescribe controlled drugs in accordance with regulation 6C;

"podiatrist independent prescriber" has the same meaning as in the Human Medicines Regulations $2012(\mathbf{d})$, and such a person may only prescribe controlled drugs in accordance with regulation 6C;";

(f) after the definition of "prescription" insert—

""prison" means any prison, young offenders centre or remand centre which is under the general superintendence of, or is provided by, the Department of Justice under the Prison Act (Northern Ireland) 1953(**e**);";

(g) for the definition of "pharmacist independent prescriber" substitute-

""pharmacist independent prescriber" has the same meaning as in the Human Medicines Regulations 2012, and such a person may only prescribe controlled drugs in accordance with regulation 6B;";

- (h) omit the definition of "registered chiropodist";
- (i) after the definition of "registered physiotherapist" insert-

""registered podiatrist" has the same meaning as in the Human Medicines Regulations $2012(\mathbf{f})$;".

Amendment of regulation 6

4. In regulation 6 (general authority to supply and possess)—

- (a) in paragraph (2) for "an extended formulary nurse prescriber" substitute "a nurse independent prescriber";
- (b) in paragraph (2) after "pharmacist independent prescriber," insert "a physiotherapist independent prescriber, and a podiatrist independent prescriber,";
- (c) after paragraph (7) insert—

"(8) Notwithstanding the provisions of section 4(1)(b) of the Act, a person lawfully conducting a retail pharmacy business may supply or offer to supply medicines containing phenobarbital or phenobarbital sodium provided that the medicine is supplied (or in the case of an offer to supply would be supplied) in accordance with conditions A to E of regulation 224 or 225 of the Human Medicines Regulations 2012(g)."

- (c) S.I. 2012/1916. Definition was inserted by S.I. 2013/1855, regulation 3(a)(viii)
- (d) S.I. 2012/1916. Definition was inserted by S.I. 2013/1855, regulation 3(a)(viii)
- (e) 1953 c. 18 (N.I.)

(g) S.I. 2012/1916

⁽a) S.I. 2003/431 (N.I. 9)

⁽b) S.R. 1995 No. 143; the Trust was renamed by section 1(3)(a) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 c. 1 (N.I.)

⁽f) S.I. 2012/1916. Definition was inserted by S.I. 2016/186, regulation 3(2)(c)

New regulation 6C

5. After regulation 6B. (Authority for Nurse Independent Prescribers and Pharmacist Independent Prescribers to prescribe) insert—

"6C. Authority for Physiotherapist Independent Prescribers and Podiatrist Independent Prescribers to prescribe

(1) A physiotherapist independent prescriber may prescribe any of the following controlled drugs for the treatment of organic disease or injury provided that the controlled drug is prescribed to be administered by the specified method—

- (a) Diazepam by oral administration;
- (b) Dihydrocodeine by oral administration;
- (c) Fentanyl by transdermal administration;
- (d) Lorazepam by oral administration;
- (e) Morphine by oral administration or by injection;
- (f) Oxycodone by oral administration;
- (g) Temazepam by oral administration.

(2) A podiatrist independent prescriber may prescribe any of the following controlled drugs for the treatment of organic disease or injury provided that the controlled drug is prescribed to be administered by the specified method—

- (a) Diazepam by oral administration;
- (b) Dihydrocodeine by oral administration;
- (c) Lorazepam by oral administration;
- (d) Temazepam by oral administration.".

Amendment of regulation 7

6. After regulation 7(7) insert—

"(8) Notwithstanding the provisions of paragraph (3), a physiotherapist independent prescriber or podiatrist independent prescriber may administer to a patient without the directions of a doctor or a dentist, any controlled drug which such physiotherapist independent prescriber or podiatrist independent prescriber respectively may prescribe under regulation 6C, provided it is administered for a purpose for which it may be prescribed under that regulation and by the method by which it was prescribed to be administered.

(9) Notwithstanding the provisions of paragraph (3), any person may administer to a patient, in accordance with the specific instructions of a physiotherapist independent prescriber or podiatrist independent prescriber, any controlled drug which such physiotherapist independent prescriber or podiatrist independent prescriber may prescribe under regulation 6C, provided it is administered for a purpose for which it may by prescribed under that regulation and by the method by which it was prescribed to be administered.".

Amendment of regulation 8

7. In regulation 8 (production and supply of drugs in Schedules 2 and 5)—

- (a) after paragraph (2)(d) insert—
 - "(da) the person in charge or acting person in charge of an organisation providing ambulance services;";
- (b) for paragraph (2)(e) substitute—
 - "(e) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at a hospital, nursing home, juvenile justice

centre or prison, the senior registered nurse, acting senior registered nurse, or registered midwife, for the time being in charge of a ward, theatre or other department in the hospital, nursing home, juvenile justice centre or prison;";

- (c) in paragraph (2)(i) for "a hospital" substitute "a hospital, organisation providing ambulance services";
- (d) in paragraph (2)(ii) for "senior registered nurse or acting senior registered nurse" substitute "senior registered nurse, acting senior registered nurse or registered midwife", and for "pharmacist independent prescriber; or" substitute "pharmacist independent prescriber;";
- (e) in paragraph (2)(iii) for "pharmacist independent prescriber." substitute "pharmacist independent prescriber; or";
- (f) after paragraph (2)(iii) insert—
 - "(iv) the person in charge or acting person in charge of an organisation providing ambulance services to supply any drug other than directly to a registered paramedic employed by the organisation for the immediate treatment of sick or injured persons.".

Amendment of regulation 9

8. In regulation 9 (production and supply of drugs in Schedules 3 and 4)—

- (a) in paragraph (3)(b) for "a hospital" substitute "a hospital, organisation providing ambulance services";
- (b) for paragraph (3)(c) substitute—
 - "(c) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at that hospital, nursing home, juvenile justice centre or prison, the senior registered nurse, acting senior registered nurse or registered midwife, for the time being in charge of a ward, theatre or other department in the hospital, nursing home, juvenile justice centre or prison.";
- (c) in paragraph (3)(i) for "a hospital" substitute "a hospital, organisation providing ambulance services";
- (d) in paragraph (3)(ii) for "senior registered nurse or acting senior registered nurse" substitute "senior registered nurse, acting senior registered nurse or registered midwife", and for "pharmacist independent prescriber; or" substitute "pharmacist independent prescriber;";
- (e) in paragraph (3)(iii) for "pharmacist independent prescriber." substitute "pharmacist independent prescriber; or";
- (f) after paragraph 3(iii) insert—
 - "(iv) the person in charge or acting person in charge of an organisation providing ambulance services to supply any drug other than directly to a registered paramedic employed by the organisation for the immediate treatment of sick or injured persons.".

Amendment of regulation 14

9. In regulation 14 (documents to be obtained by supplier of controlled drugs)—

- (a) after paragraph (2)(a)(iv) insert—
 - "(v) is in the form approved by the Department, for the purposes of requisitioning Schedule 2 and 3 controlled drugs;";
- (b) in paragraph (4)(b) for "a hospital" substitute "a hospital, organisation providing ambulance services";
- (c) in paragraph (4)(i) for "pharmacist independent prescriber." substitute "pharmacist independent prescriber;";

- (d) after paragraph (4)(i) insert—
 - "(j) a person who holds a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Department, or a person who is a registered paramedic.";
- (e) for paragraph (5)(a) substitute—
 - "(a) where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or nursing home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or nursing home;";
- (f) in paragraph (5B)(b) for "hospital or nursing home" substitute "hospital, organisation providing ambulance services, nursing home, juvenile justice centre or prison.";
- (g) in paragraph (6) for "any hospital or nursing home supplies a controlled drug to the senior registered nurse or acting senior registered nurse for the time being in charge of any ward, theatre or other department in that hospital or nursing home"(a) substitute "any hospital, nursing home, juvenile justice centre or prison supplies a controlled drug to an operating department practitioner, senior registered nurse, acting senior registered nurse, or registered midwife, for the time being in charge of any ward, theatre or other department in that hospital, nursing home, juvenile justice centre or prison";
- (h) in paragraph (7)(c) for "product." substitute "product;";
- (i) after paragraph (7)(c) insert—

"(d) subject to paragraph (6) any drug which is required—

- (i) for use in a juvenile justice centre or prison; or
- (ii) for use in an institution, which as its whole or main purpose provides palliative care for persons resident there who are suffering from a progressive disease in its final stages.".

Amendment of regulation 15

10. In regulation 15 (form of prescriptions)—

- (a) in paragraph (1)(d) after "his care" insert "and specify the Royal College of Veterinary Surgeons registration number of the veterinary surgeon or veterinary practitioner issuing it";
- (b) omit paragraph (1A);
- (c) in paragraph (3) for "hospital or nursing home" substitute "hospital, nursing home, juvenile justice centre or prison".

Amendment of regulation 19

11. For regulation 19(3)(c) (record-keeping requirements in respect of drugs in Schedules 1 and 2) substitute—

"(c) the senior registered nurse, acting senior registered nurse or registered midwife, for the time being in charge of a ward, theatre or other department in a hospital, nursing home, juvenile justice centre or prison.".

Amendment of regulation 24

12. In regulation 24(3) (preservation of records relating to drugs in Schedules 3 and 5) for "a hospital" substitute "a hospital, organisation providing ambulance services".

⁽a) The reference to "senior registered nurse or acting senior registered nurse", was inserted by regulation 5(3) of S.R. 2007 No. 348

Amendment of regulation 26

13. In regulation 26(2)(f) (furnishing of information with respect to controlled drugs) for "a hospital" substitute "a hospital, organisation providing ambulance services".

Amendment of Schedule 1

14. In Schedule 1 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 23, 26 and 27)—

- (a) omit paragraph 1(ca)(**a**);
- (b) after paragraph 1(lc) insert—
 - "(ld)Any compound (not being a compound for the time being specified in subparagraphs (h) to (lc) above) structurally related to 1-pentyl-3-(1naphthoyl)indole (JWH-018), in that the four sub-structures, that is to say the indole ring, the pentyl substituent, the methanone linking group and the naphthyl ring, are linked together in a similar manner, whether or not any of the sub-structures have been modified, and whether or not substituted in any of the linked sub-structures with a benzyl or phenyl group and whether or not such compound is further substituted to any extent with alkyl, alkenyl, alkoxy, halide, haloalkyl or cyano substituents and, where any of the sub-structures have been modified, the modifications of the substructures are limited to any of the following, that is to say—
 - (i) replacement of the indole ring with indane, indene, indazole, pyrrole, pyrazole, imidazole, benzimidazole, pyrrolo[2,3-b]pyridine, pyrrolo[3,2-c]pyridine or pyrazolo[3,4-b]pyridine;
 - (ii) replacement of the pentyl substituent with alkyl, alkenyl, benzyl, cycloalkymethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl, 2-(4-morpholinyl)ethyl or (tetrahydropyran-4-yl)methyl;
 - (iii) replacement of the methanone linking group with an ethanone, carboxamide, carboxylate, methylene bridge or methine group;
 - (iv) replacement of the 1-naphthyl ring with 2-naphthyl, phenyl, benzyl, adamantyl, cycloalkyl, cycloalkylmethyl, cycloalkylethyl, bicyclo[2.2.1]heptanyl, 1,2,3,4-tetrahydronaphthyl, quinolinyl, isoquinolinyl, 1-amino-1-oxopropan-2-yl, 1-hydroxy-1-oxopropan-2-yl, piperidinyl, morpholinyl, pyrrolidinyl, tetrahydropyranyl or piperazinyl.".

Amendment of Schedule 8

15. In paragraph 1(e) for "a registered chiropodist" substitute "a registered podiatrist".

Transitional provisions

16. Where a supplier obtained a requisition under regulation 14(2) of the Misuse of Drugs Regulations (Northern Ireland) 2002 before 15 November 2019, regulation 9(a) of these Regulations does not apply in respect of that requisition.

17. In the case of a prescription issued under regulation 15(1)(d) of the Misuse of Drugs Regulations (Northern Ireland) 2002 before 15 November 2019, regulation 16(1)(a) of those Regulations has effect as if regulation 15(1)(d) had not been amended by these Regulations.

⁽a) Paragraph 1(ca) was inserted by the Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2018 (S.R. 2018 No. 4), regulation 2(3)

Sealed with the Official Seal of the Department of Health on 24th October 2019



Cathy Harrison A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations (Northern Ireland) 2002 (the "2002 Regulations").

The 2002 Regulations are amended by including within the definition of "health prescription" contained in regulation 2(2), physiotherapist independent prescriber and podiatrist independent prescriber as persons who may issue such a prescription. They also insert definitions of "juvenile justice centre", "nursing home", "organisation providing ambulance services", "physiotherapist independent prescriber" and "prison" in regulation 2(2).

Regulations 6 and 7 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".

Regulation 8 is amended by including within paragraph (2), in relation to the supply or offer to supply any drug specified in Schedule 2 or 5 to the 2002 Regulations in certain circumstances, 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 senior registered nurse, acting senior registered nurse or registered midwife.

Regulation 9 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 in certain circumstances, by a person who is in charge, or is acting person in charge, of an organisation providing ambulance services.

Regulation 14 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. A person who is in charge, or is acting person in charge, of an organisation providing ambulance services, and a person who holds a certificate of proficiency in ambulance paramedic skills are added to the list of recipients in regulation 14(4). The requisition required under regulation 14(6) applying when a controlled drug is supplied, in any hospital or nursing home, 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).

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.

Regulation 19(3) is amended to include a registered midwife in the range of persons to whom the record-keeping requirements contained in regulation 19 shall not have effect, and to include juvenile justice centres and prisons within this exemption.

Regulations 24 and 26, 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.

Schedule 1 to the 2002 Regulations is amended 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).

Paragraph 1(e) of Schedule 8 is amended by replacing "a registered chiropodist" with "a registered podiatrist". The term "podiatrist" is synonymous and interchangeable with "chiropodist" and both are required to adhere to the same professional standards against which they are regulated.

Regulations 16 and 17 of these amending Regulations (Transitional provisions) state that 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 and the 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 prior to 15 November 2019.

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