STATUTORY INSTRUMENTS.

S.I. No. 522 of 2017

MISUSE OF DRUGS (SUPERVISION OF PRESCRIPTION AND SUPPLY OF METHADONE AND MEDICINAL PRODUCTS CONTAINING BUPRENORPHINE AUTHORISED FOR OPIOID SUBSTITUTION TREATMENT) REGULATIONS 2017

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I, CATHERINE BYRNE, Minister of State at the Department of Health, in exercise of the powers conferred on me by section 5 (as amended by section 15 of the Misuse of Drugs Act 1984 (No. 18 of 1984) and section 3 of the Misuse of Drugs (Amendment) Act 2016 (No. 9 of 2016)) of the Misuse of Drugs Act 1977 (No. 12 of 1977) and the Health (Delegation of Ministerial Functions) (No. 4) Order 2017 (S.I. No. 339 of 2017), hereby make the following regulations:

Citation and commencement

1. (1) These Regulations may be cited as the Misuse of Drugs (Supervision of Prescription and Supply of Methadone and Medicinal Products containing Buprenorphine authorised for Opioid Substitution Treatment) Regulations 2017.

(2) These Regulations shall come into operation on 22 November 2017.

Interpretation

2. In these Regulations—

"Central Treatment List" means the record referred to in Regulation 3(2);

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[1];

"Executive" means Health Service Executive;

"Minister" means Minister for Health;

"marketing authorisation" means an authorisation or licence which is for the time being in force and which has been granted by—

(*a*) the Health Products Regulatory Authority in accordance with—

(i) the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), including a product authorisation or a parallel import licence, or

(ii) Article 126a of Directive 2001/83/EC,

[1]OJ No. L 311, 28.11.2001, p. 67.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 28*th November*, 2017.

(*b*) the European Commission under Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004[2],

(*c*) the competent authority of a state which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992, as adjusted by the Protocol to that Agreement done at Brussels on 17 March 1993, in accordance with Article 6 of Directive 2001/83/EC, or

(*d*) the competent authority in the Swiss Confederation for the granting of authorisations or licences for the marketing of medicinal products;

"person carrying on a retail pharmacy business" means a person carrying on a retail pharmacy business in accordance with section 26(1) of the Pharmacy Act 2007 (No. 20 of 2007);

"prescription" means a prescription issued by a registered medical practitioner in compliance with Regulation 15 of the Principal Regulations;

"opioid substitution treatment card" means a card issued pursuant to Regulation 4;

"Principal Regulations" means the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017);

"registered medical practitioner" means a medical practitioner registered by the Medical Council under Part 6 of the Medical Practitioners Act 2007 (No. 25 of 2007);

"Regulations of 1998" means the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No. 225 of 1998);

"retail pharmacy business" has the meaning assigned to it by the Pharmacy Act 2007;

"specified controlled drug" means a drug specified in the Schedule.

Central Treatment List

3. (1) Where a registered medical practitioner intends to prescribe a specified controlled drug for opioid substitution treatment for the first time to a person who has presented to the registered medical practitioner for treatment, the registered medical practitioner shall not issue a prescription for the drug until he or she notifies the Executive of the name, address and date of birth of the person.

(2) The Executive shall continue to maintain the record known, and in these Regulations referred to, as the "Central Treatment List", which list it maintained in accordance with Regulation 3 of the Regulations of 1998, and shall add to such list the information notified to it under paragraph (1), and such list may be maintained in electronic form.

[2]OJ No. L 136, 30.4.2004, p. 1.

(3) Where a notification is made to the Executive in accordance with paragraph (1), the Executive shall inform the registered medical practitioner as to whether the person has previously been included in the Central Treatment List.

(4) The Executive may amend an entry in, or delete an entry from, the Central Treatment List.

Issue of opioid substitution treatment card

4. (1) The Executive shall issue a card to be known, and in these Regulations referred to, as an "opioid substitution treatment card" in respect of a person participating in a programme of treatment involving the use of a specified controlled drug and in respect of whom the information referred to in Regulation 3(1) has been notified to the Executive.

(2) An opioid substitution treatment card shall be valid for such period as may be specified on the card but in any case shall not be valid for more than one year from the date of issue.

General prohibition on registered medical practitioner

5. (1) A registered medical practitioner shall not issue a prescription for a specified controlled drug other than on a form supplied by or on behalf of the Executive.

(2) A registered medical practitioner shall not issue a prescription referred to in paragraph (1) other than to a person in respect of whom an opioid substitution treatment card has been issued and remains valid.

General prohibition on person carrying on a retail pharmacy business

6. (1) A person carrying on a retail pharmacy business shall not supply a specified controlled drug on a prescription other than on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1).

(2) A person carrying on a retail pharmacy business shall not supply a specified controlled drug on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1) other than to a person in respect of whom an opioid substitution treatment card has issued and remains valid.

Information to be furnished to Executive

7. A person carrying on a retail pharmacy business shall forward to the Executive—

(*a*) in respect of each supply of a specified controlled drug on prescription—

(i) the original prescription on which the supply of the specified controlled drug was made, and

(ii) if the information given on the prescription is inadequate, illegible or misleading, a statement which confirms or clarifies the identity of the person to whom the prescription was issued, and

(*b*) in respect of each supply of a specified controlled drug made to a registered medical practitioner pursuant to a requisition referred to in Regulation 14(2) of the Principal Regulations, particulars, including the purpose, of the supply,

not later than 14 days after the last day of the calendar month in which the supply of the specified controlled drug was completed or, in the case of supply on prescription, when no further supply may be made on that prescription.

Executive to maintain a record

8. (1) The Executive shall maintain a record of all prescriptions, statements and particulars received under Regulation 7 and the record may be maintained in an electronic form.

(2) Subject to paragraph (3), the Executive may amend an entry in, or delete an entry from, the record referred to in paragraph (1).

(3) Each prescription, statement or particular received by the Executive under Regulation 7 shall be preserved for a period of two years from the date of receipt.

Prohibition on supply

9. (1) A person shall not supply a specified controlled drug to a registered medical practitioner unless that person is a person carrying on a retail pharmacy business.

(2) Paragraph (1) shall not apply to a person who is the holder of a licence under section 14 of the Misuse of Drugs Act 1977 (No. 12 of 1977) to supply a controlled drug, where the licence directs that such supply may be made.

Supply by instalments

10. (1) For the purposes of compliance with Regulation 19(1) of the Principal Regulations, where the supply of a specified controlled drug on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1) is to be dispensed in instalments-

(*a*) the information in relation to each supply may be entered on the prescription, and

(*b*) the total amount supplied on the prescription, when the dispensing of that prescription has been completed or when no further supply may be made on that prescription, may be entered, in the register referred to in Regulation 19(1) of the Principal Regulations, as the amount supplied.

(2) For the purposes of an entry in a register to be made under paragraph (1), the date to be entered in the register shall be the date on which the last supply was made on the prescription concerned.

Preservation of records

11. Notwithstanding Regulation 22(2) of the Principal Regulations, the preservation of a copy of a prescription issued by a registered medical practitioner in accordance with Regulation 5(1), made by a registered medical practitioner at the time of writing the original prescription, shall be treated as if it were the preservation of the original prescription.

Exemption: hospitals

12. (1) These Regulations shall not apply to a prescription issued in respect of a specified controlled drug where the prescription has been issued in a hospital—

(*a*) for administration in the hospital, to the person to whom the prescription relates, or

(*b*) for supply in the hospital, in exceptional circumstances, to the person to whom the prescription relates and who has attended the hospital—

(i) for the treatment of opioid dependence, or

(ii) as an in-patient who is opioid dependent.

(2) When opioid substitution treatment is initiated in the hospital, the hospital shall notify the Executive of the name, address and date of birth of the person in respect of whom treatment is initiated.

(3) In this Regulation "hospital" means a hospital, nursing home or clinic which is wholly or mainly maintained by a public authority out of public funds, by a charity or by voluntary subscriptions.

Exemption: medical consultants

13. (1) Regulations 3, 4, 5(2) and 6(2) shall not apply to a prescription for the treatment of a person for purposes other than for or in connection with opioid dependence provided that—

(*a*) the prescription has been initiated, for issue by a registered medical practitioner, by a medical consultant whose name and address is included on the prescription, or

(*b*) the prescription is issued by the medical consultant.

(2) In this Regulation "medical consultant" means a medical practitioner in any hospital practice registered in the Specialist Division of the register of medical practitioners established and maintained by the Medical Council under section 43 of the Medical Practitioners Act 2007, who by reason of his or her training, skill and experience in a particular specialty, is consulted by other registered medical practitioners and who has a continuing clinical and professional responsibility for patients under his or her care, or that aspect of their care on which he or she has been consulted.

Transitional provisions

14. (1) A reference in any other enactment to the Regulations of 1998 shall be construed as a reference to these Regulations.

(2) Notwithstanding Regulation 5(2), a registered medical practitioner may issue a prescription for a specified controlled drug to a person in respect of whom an opioid substitution treatment card has not been issued where—

(*a*) a drug treatment card in respect of that person was issued under Regulation 4(1) of the Regulations of 1998 for the use of such specified controlled drug, and

(*b*) the period specified on such card within which that card would remain valid has not expired.

(3) Notwithstanding Regulation 6(1), a person carrying on a retail pharmacy business may supply a specified controlled drug on a prescription other than on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1) where the prescription was issued by a registered medical practitioner in accordance with Regulation 5(1) of the Regulations of 1998.

(4) Notwithstanding the revocation of the Regulations of 1998, a person carrying on a retail pharmacy business may supply a specified controlled drug on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1) of those Regulations where—

(*a*) the prescription was issued to a person in respect of whom a drug treatment card was issued under Regulation 4(1) of those Regulations for the use of such specified controlled drug, and

(*b*) the period specified on such card within which that card would remain valid has not expired.

(5) Notwithstanding the revocation of the Regulations of 1998, the Minister shall preserve any remaining records made in accordance with Regulation 8 of those Regulations for the period specified under paragraph (3) of that Regulation.

SCHEDULE

Regulation 2

1. Methadone

2. Any stereoisomeric form of a substance specified in paragraph (1).

3. Any salt of a substance specified in paragraph 1or 2.

4. Any preparation or other product containing any proportion of a substance or product specified in paragraphs 1, 2 or 3.

5. Any medicinal product containing buprenorphine with a marketing authorisation indicated for substitution treatment for opioid drug dependence.

GIVEN under my hand
22 November 2017.

CATHERINE BYRNE,
Minister of State at the Department of Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations replace the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No 225 of 1998). The Regulations add certain buprenorphine medicinal products authorised for opioid substitution treatment to the Schedule of products which fall within the scope of these Regulations.

These Regulations also update a number of references and definitions, replace the Minister with the Health Service Executive for the purposes of receiving information and reassign responsibilities relating to maintenance of records from the Minister to the Health Service Executive.

These Regulations may be cited as the Misuse of Drugs (Supervision of Prescription and Supply of Methadone and Medicinal Products containing buprenorphine authorised for Opioid Substitution Treatment) Regulations 2017.

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