STATUTORY INSTRUMENTS.

S.I. No. 262 of 2019

MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) REGULATIONS 2019

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I, Simon Harris, Minister for Health, in exercise of the powers conferred on me by sections 4 and 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), hereby make the following regulations:

PART 1

PRELIMINARY

Citation

1. These Regulations may be cited as the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019.

Definitions

2. In these Regulations–

"adverse reaction" means a response to a specified controlled drug which is noxious and unintended;

"Authority" means the Health Products Regulatory Authority;

"CMUR number" means the number assigned to a person under Regulation 5(4) on entry of the person's name in the Cannabis for Medical Use Register;

"Cannabis for Medical Use Register" means the register established and maintained by the Executive pursuant to Regulation 5;

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

"Executive" means the Health Service Executive;

"medical consultant" means a registered medical practitioner who—

(*a*) is registered on 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 (No. 25 of 2007), and

(*b*) by reason of his or her training, skill and experience in a medical specialty recognised by the Medical Council under section 89(1) of that Act related to a specified therapeutic indication, is consulted by other registered medical practitioners and has a

[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 June,* 2019.

continuing clinical and professional responsibility for that aspect of the patient's care on which he or she has been consulted;

"medicinal product" has the meaning assigned to it by Directive 2001/83/EC, as amended from time to time;

"Member State" means 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[2];

"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);

"practitioner" means a registered medical practitioner;

"Principal Act" means the Misuse of Drugs Act 1977 (No. 12 of 1977);

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

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

"produce", where the reference is to producing or production of a specified controlled drug, means produce by cultivation, manufacture, synthesis or any other method;

"registration number" has the meaning assigned to it by the Principal Regulations;

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

"serious adverse reaction" means an adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect;

"specified controlled drug" means a cannabis product or preparation—

(*a*) which is produced from dried, ground or powdered flower of Cannabis,

(*b*) which is not a medicinal product which is the subject of a marketing authorisation within the meaning assigned to that term in Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007),

(*c*) which—

(i) Contains not more than 230 milligrams of tetrahydrocannabinol per gram and not more than 5 grams per pack, or

(ii) is presented as an oil-based solution, suspension or capsule, and has a concentration of not more than 30 milligrams of

[2] OJ No. L 1, 3.1.1994, p. 572.

tetrahydrocannabinol per millilitre (3% w/v) per unit dose and a total volume of not more than 60 millilitres,

(*d*) which is permitted to be sold or supplied for medical purposes by the relevant public or state body of a Member State other than the State,

(*e*) which is currently supplied to patients in the Member State referred to in sub-paragraph (d),

(*f*) which is packaged and labelled in the English language and in accordance with guidance on labelling and packaging as published by the Authority, and

(*g*) which is specified in Schedule 1;

"specified therapeutic indication" means a therapeutic indication specified in Schedule 2.

PART 2

PRESCRIPTION AND SUPPLY UNDER CANNABIS FOR MEDICAL USE REGISTER

Scope of Part 2

3. This Part does not apply to the prescribing of a particular specified controlled drug pursuant to a licence issued by the Minister under section 14 of the Principal Act, or to the importation, possession, supply or administration of such drug pursuant to such licence.

Restrictions on issuing of prescriptions for specified controlled drugs

4. (1) A practitioner shall not issue a prescription for a specified controlled drug other than where—

(*a*) the practitioner is a medical consultant,

(*b*) the practitioner's name and address are included on the prescription, and

(*c*) treatment with the specified controlled drug remains under the supervision of that practitioner.

(2) A practitioner shall not issue a prescription for a specified controlled drug other than to a person whose name has been entered in the Cannabis for Medical Use Register and who has received a CMUR number from the Executive.

(3) Subject to paragraph (5), a practitioner shall not issue a prescription for a specified controlled drug other than in a format prescribed by the Executive for that purpose.

(4) Subject to paragraph (5), a practitioner shall not issue a prescription for a specified controlled drug without including in the prescription the CMUR number of the person to whom the prescription is to be issued.

(5) Paragraphs (3) and (4) do not apply in the case of supply of a specified controlled drug pursuant to Regulation 6(3)(a).

(6) A practitioner shall not issue a prescription for a specified controlled drug for the first time to a person under his or her care unless—

(*a*) the specified controlled drug is intended to treat that person for a specified therapeutic indication, and

(*b*) the practitioner has notified the Executive, in such form as it may require, including electronically, of—

(i) the name, address, date of birth and specified therapeutic indication of the person,

(ii) the name, registration number and medical specialty of the notifying practitioner, and

(iii) such additional information as the Executive may require.

(7) A practitioner issuing a prescription for a specified controlled drug for use by his or her individual patient does so under his or her direct responsibility in order to fulfil the special needs of that patient.

(8) The fact that a product is a specified controlled drug is not an endorsement of the safety, quality or efficacy of the specified controlled drug and the Minister shall have no liability in respect of the use of a specified controlled drug by a person issued with a prescription under this Regulation.

Cannabis for Medical Use Register

5. (1) The Executive shall establish and maintain a register, to be known as the "Cannabis for Medical Use Register", which shall contain the information notified to it under Regulation 4(6)(b), and such register may be maintained in electronic form.

(2) The Executive may amend an entry in, or delete an entry from, the Cannabis for Medical Use Register.

(3) The Executive may, before inserting, amending or deleting an entry in the Cannabis for Medical Use Register, require the medical consultant supervising the treatment to provide such additional information as is considered necessary.

(4) The Executive shall assign a number ("CMUR number") to each person whose name is entered in the Cannabis for Medical Use Register under this Regulation.

Supply of specified controlled drugs

6. (1) A person shall not supply a specified controlled drug to a practitioner unless the person supplying is—

(*a*) a pharmacist acting in his or her capacity as such, or

(*b*) a person carrying on a retail pharmacy business,

and the supply is made for the purpose of his or her profession or business.

(2) A person shall not supply a specified controlled drug to a person other than a practitioner unless the person supplying is—

(*a*) a pharmacist acting in his or her capacity as such, or

(*b*) a person carrying on a retail pharmacy business,

and the supply is made—

(i) for the purpose of his or her profession or business,

(ii) in the case of a person referred to in subparagraph (b), at the premises at which he or she carries on such business,

(iii) by or under the personal supervision of a pharmacist, and

(iv) on a prescription issued by a practitioner in accordance with Regulation 4.

(3) A person supplying specified controlled drugs in a hospital shall not supply a specified controlled drug prescribed in the hospital other than—

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

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

(i) as an in-patient, or

(ii) for the treatment of a specified therapeutic indication.

(4) All references to a "medicinal product" in Regulation 9 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), as amended from time to time, shall be construed as a reference to a specified controlled drug, and a person shall not dispense or supply a specified controlled drug other than in accordance with the requirements of that provision.

(5) All references to a "medicinal product" in Regulations 5(1)(d) and 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), as amended from time to time, shall be construed as a reference to a specified controlled drug, and a person shall not dispense or supply a specified controlled drug other than in accordance with the requirements of that provision.

(6) A person supplying a specified controlled drug shall not make the drug accessible to the public for self-selection.

Record keeping by suppliers of specified controlled drugs

7. A person carrying on a retail pharmacy business shall preserve and keep readily available for inspection at the premises at which he or she carries on such business, in relation to each supply of a specified controlled drug by his or her business—

(*a*) the prescription, or a copy thereof, and

(*b*) the following particulars:

(i) the date on which the supply was made;
(ii) the name, quantity and, except where this is apparent from the name, the dosage form and strength of the specified controlled drug supplied;
(iii) the dose of the specified controlled drug supplied;
(iv) the name, address and registration number of the prescriber;
(v) the CMUR number, name and address of the person for whom the specified controlled drug is prescribed; and
(vi) the date of the prescription.

Information to be furnished to the Executive in relation to the supply of specified controlled drugs

8. A person supplying a specified controlled drug pursuant to Regulation 6 shall forward to the Executive, in respect of each supply of the drug—

(*a*) his or her name and address,

(*b*) the name and address of the person who supplied him or her with the specified controlled drug,

(*c*) the particulars of the prescription, as listed at Regulation 7(b), which the supply was made against, and

(*d*) any further information required by the Executive,

in such form as the Executive may require, not later than 14 days after the last day of the calendar month in which the supply took place.

Recording of supply of specified controlled drugs by the Executive

9. (1) The Executive shall maintain a record of all particulars of supply of specified controlled drugs received under Regulation 8 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 a record referred to in paragraph (1).

(3) Each record referred to in paragraph (1) shall be preserved for a period not less than five years from the date of receipt of the particulars recorded.

PART 3

COMMERCIAL SUPPLY UNDER LICENCE

Scope of this Part

10. (1) Subject to paragraph (2), this Part applies to the supplying or importing of a specified controlled drug by the holder of a licence issued by the Minister under section 14 of the Principal Act.

(2) This Part does not apply to the supplying or importation of a particular specified controlled drug where the prescribing of that specified controlled drug is pursuant to a licence issued by the Minister under section 14 of the Principal Act.

Restriction on supply of specified controlled drugs

11. A person shall not supply a specified controlled drug unless the person being supplied is—

(a) a pharmacist acting in his or her capacity as such,

(b) a person carrying on a retail pharmacy business, or

(c) a hospital,

and, in the case of supply to a person referred to in paragraph (a) or (b), the supply is made for the purpose of the profession or business of the person supplied.

Record keeping by persons supplying or importing specified controlled drugs

12. (1) A person supplying or importing a specified controlled drug shall, in the case of each consignment of the drug received by him or her, make, and keep available for review by the Minister for a period of not less than five years from the date of receipt, written records showing the following particulars:

(a) the name of the drug, including the brand name as detailed on the product packaging;

(b) the dosage form of the drug;

(c) the quantity of the drug which has been received;

(d) the batch number of the drug which has been received; and

(e) the name and address of the producer of that specified controlled drug in the form in which it was received and the name and address of the supplier of each consignment.

(2) A person supplying or importing a specified controlled drug shall, in the case of each consignment of the drug supplied by him or her, make, and keep available for review by the Minister for a period of not less than five years from the date of supply, written records showing the following particulars:

(*a*) the name of the drug, including the brand name as detailed on the product packaging;

(*b*) the dosage form of the drug;

(*c*) the quantity of the drug which has been supplied;

(*d*) the batch number of the drug which has been supplied; and

(e) the name and address of the person to whom the drug has been supplied.

Prohibition of exporting imported specified controlled drugs

13. A person who imports a specified controlled drug shall not export that specified controlled drug outside of the State.

PART 4

REPORTING, ENFORCEMENT AND ADVERTISING

Scope of Part 4

14. This Part applies to a person prescribing, supplying or importing a specified controlled drug within the scope of Part 2 or Part 3.

Reporting of suspected adverse reactions and quality defects

15. (1) A person shall—

(*a*) make a detailed report of any suspected adverse reaction to the specified controlled drug which is brought to his or her attention,

(*b*) report to the Authority any suspected serious adverse reaction no later than 15 days following receipt of the information concerned, and any other adverse reaction no later than 90 days following receipt of the information concerned, and

(c) provide to the Authority any other information relevant to the safety of the specified controlled drug.

(2) A person shall make a detailed report to the Authority on any critical or serious quality defect in a timely manner but no later than 15 days following receipt of the information concerned, and on any other quality defect no later than 90 days following receipt of the information concerned of any quality defects, coming to his or her attention, in respect of a specified controlled drug.

(3) Where a report is made to the Authority under this Regulation, such report shall, except in exceptional circumstances, be communicated electronically to the Authority and shall be in the form of a report prepared and presented in accordance with guidelines to be provided by the Authority.

(4) A person who makes a report under this Regulation shall retain written records of the adverse reaction or quality defect for a period of not less than 5 years after he or she becomes aware of same.

Withdrawal and recall of specified controlled drugs

16. (1) Where the Authority becomes aware of quality or safety issues relating to a specified controlled drug, or a batch or part of a batch thereof, it may direct the withdrawal and recall of the specified controlled drug from the market.

(2) Where a person prescribing, supplying or importing a specified controlled drug under Part 2 or Part 3 considers that there may be grounds for the withdrawal and recall of the specified controlled drug from the market under this Regulation, he or she shall immediately inform the Authority.

Prohibition on prescribing, supplying or importing

17. A person prescribing, supplying or importing a specified controlled drug under Part 2 or Part 3 shall cease such action if he or she has received a notice in writing from the Minister or from the Authority directing that, as from a date specified in that notice, the specified controlled drug shall no longer be supplied or imported.

Restrictions on advertising of specified controlled drugs

18. (1) A person shall not issue an advertisement or representation relating to a specified controlled drug with a view to it being seen by the general public in the State.

(2) A person shall not supply information relating to a specified controlled drug otherwise that in response to a bona fide unsolicited order.

SCHEDULE 1

Regulation 2

Specified Controlled Drugs

Name of Cannabis product or preparation and brand name	**Dosage form**	**Concentration of THC (percentage, weight/weight or weight/volume)**	**Name of manufacturer/supplier**

SCHEDULE 2

Regulation 2

Specified therapeutic indications

1. Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions.

2. Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes.

3. Severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications.

L.S.

GIVEN under my Official Seal,
26 June 2019.

SIMON HARRIS

Minister for Health

EXPLANATORY NOTE

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

The purpose of these Regulations is to allow certain cannabis products or preparations for medical use to be prescribed and supplied under certain circumstances for the treatment of persons with certain medical conditions under the care of a medical consultant.

These Regulations may be cited as the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019.

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