



STATUTORY INSTRUMENTS.

S.I. No. 173 of 2017



MISUSE OF DRUGS REGULATIONS 2017

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MISUSE OF DRUGS REGULATIONS 2017

I, CATHERINE BYRNE, Minister of State at the Department of Health, in exercise of the powers conferred on me by sections 4, 5 (as amended by section 15 of the Misuse of Drugs Act 1984 (No. 18 of 1984), section 4 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and section 3 of the Misuse of Drugs (Amendment) Act 2016 (No. 9 of 2016)), 18 and 38 of the Misuse of Drugs Act 1977 (No. 12 of 1977), section 5 of the Misuse of Drugs Act 1984 and the Health (Delegation of Ministerial Functions) (No. 3) Order 2016 (S.I. No. 511 of 2016), hereby make the following regulations:

PART 1

PRELIMINARY AND GENERAL

Citation and commencement

1. (1) These Regulations may be cited as the Misuse of Drugs Regulations 2017.

(2) These Regulations come into operation on 4 May 2017.

Interpretation

2. (1) In these Regulations—

“Act of 2006” means the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006);

“Acts relating to merchant shipping” means the Merchant Shipping Acts 1894 to 2014;

“authorised as a member of a group” means authorised by virtue of being a member of a class in respect of which the Minister, under section 4 of the Principal Act, has granted an authority which is in force under and for the purposes of Regulation 9(2) and “his or her group authority” in relation to a person who is a member of such a class means the authority so granted to that class;

“Director of Nursing or Director of Midwifery or Matron” includes a person acting in that capacity;

“Clinical Nurse Manager or Clinical Midwife Manager or Sister” includes a person acting in that capacity;

“Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001¹;

¹OJ No. L 311, 28.11.2001, p. 67.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 5th May, 2017.

“Executive” means the Health Service Executive;

“health prescription” and “health service requisition” mean, respectively, a prescription or a requisition issued in connection with arrangements made under section 59 of the Health Act 1970 (No. 1 of 1970) upon a form supplied by or on behalf of the Executive;

“installation manager”, “offshore installation” and “Industrial Medical Adviser (Offshore Installations)” have the meanings assigned to them by the Safety, Health and Welfare (Offshore Installations) Act 1987 (No. 18 of 1987);

“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,
- (b) the European Commission under Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004²,
- (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 1993³, 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;

“master” has the meaning assigned to it in the Acts relating to merchant shipping;

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

“the Minister” means the Minister for Health;

“officer of customs” has the meaning assigned to it by the Customs Act 2015 (No. 18 of 2015);

²OJ. No. L 136, 30.4.2004, p. 1.

³OJ No. L 1, 3.1.1994, p. 572.

“An Post” means the company referred to in section 10(1)(a) of the Postal and Telecommunications Services Act 1983 (No. 24 of 1983);

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

“practitioner” means a registered medical practitioner, a registered dentist, a registered veterinary practitioner or, subject to regulation 3, a registered nurse or registered midwife;

“prescription” means a prescription issued by—

- (a) a registered medical practitioner for the medical treatment of an individual,
- (b) a registered dentist for the dental treatment of an individual,
- (c) a registered veterinary practitioner for the purposes of animal treatment, or
- (d) subject to Regulation 3, a registered nurse or registered midwife for the medical treatment of an individual;

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

“prison” has the meaning assigned to it by the Prisons Act 2007 (No. 10 of 2007), as amended by the Prisons Act 2015 (No. 57 of 2015);

“prison officer” means an officer of the Minister for Justice and Equality assigned to perform the duties of a prison officer;

“produce”, where the reference is to producing a controlled drug, means produce by cultivation, manufacture, synthesis or any other method;

“registered veterinary practitioner” means a person registered under Part 4 of the Veterinary Practice Act 2005 (No. 22 of 2005);

“registration number” means—

- (a) in the case of a registered medical practitioner, the number attached to the medical practitioner’s registration in accordance with section 43(5) of the Medical Practitioners Act 2007 (No. 25 of 2007),
- (b) in the case of a registered veterinary practitioner, the identification number issued to the veterinary practitioner for the purposes of registration under section 37 of the Veterinary Practice Act 2005,

- (c) in the case of a registered nurse or registered midwife, the number attached to the nurse's or midwife's registration in accordance with section 46(7) of the Nurses and Midwives Act 2011 (No. 41 of 2011), or
- (d) in the case of a registered dentist, the number assigned by the Dental Council to the registration in the Register of Dentists in accordance with section 26 of the Dentists Act 1985 (No. 9 of 1985);

“Regulations of 1988” means the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (revoked by section 7 of the Misuse of Drugs (Amendment) Act 2016 (No. 9 of 2016));

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

“the State Chemist” means the head of the State Laboratory;

“wholesaler” means a person who carries on the business of selling controlled drugs to persons for the purpose of resale.

- (2) (a) Subject to subparagraph (b), in these Regulations, other than in the case of a register referred to in Regulation 9 or 10, “register” means a bound book and does not include any form of loose leaf register or card index.

(b) In the case of—

- (i) the holder of a manufacturer's authorisation, as defined in Regulation 3 of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007), where the activities to be recorded in the register are related to those subject to the principles and guidelines of good manufacturing practice as provided for in Article 47 of Directive 2001/83/EC or Article 51 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001⁴,
- (ii) an authorisation holder as defined in Regulation 4 of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007), where the activities to be recorded in the register are related to those subject to guidelines of good distribution practice as provided for in Article 84 of Directive 2001/83/EC,

the register may be an electronic register which shall be based on a computerised system equivalent to the register and which shall be validated in line with good manufacturing practice or good distribution practice, as appropriate to the activities performed.

⁴OJ No. L 311, 28.11.2001, p. 1.

PART 2

ISSUING OF PRESCRIPTIONS BY REGISTERED NURSES AND REGISTERED MIDWIVES

Provisions applicable to practitioners who are registered nurses or registered midwives.

3. (1) Notwithstanding any other provision of these Regulations but subject to paragraphs (2) and (3), a reference (howsoever expressed) in these Regulations to Schedule 2 or 3 shall, in the case of a reference in these Regulations to a registered nurse or registered midwife in the capacity of the nurse or midwife as a practitioner insofar, but only insofar, as that capacity relates to the issuing of prescriptions (and irrespective of whether the term “practitioner” or “registered nurse” or “registered midwife” is used), be construed to mean a reference to Schedule 8.

(2) A registered nurse or registered midwife shall not, in his or her capacity as a practitioner, issue a prescription for a drug specified in Schedule 4, 5 or 8 unless the following conditions are satisfied:

- (a) the nurse or midwife is employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home);
- (b) the controlled drug is a drug which would be prescribed in the usual course of the provision of the health service provided in the health service setting in which the nurse or midwife is employed;
- (c) the prescription is in fact issued in the usual course of the provision of that health service;
- (d) the prescription of the controlled drug is—
 - (i) in the case of a drug specified in Part 1 of Schedule 8—
 - (I) for the relief of acute, persistent or severe pain of a person, in a hospital or as part of the services provided by a hospital,
 - (II) for administration to a person immediately prior to a medical or surgical procedure which is carried out in a hospital or clinic, for sedation or for the prevention or relief of pain or distress of the person, or
 - (III) for the post-operative pain relief of a person in a hospital,
 - (ii) in the case of a drug specified in Part 2 of Schedule 8, for palliative care,
 - (iii) in the case of a drug specified in Part 3 of Schedule 8, for the purposes of midwifery,

- (iv) in the case of a drug specified in Part 4 of Schedule 8, for the neonatal care of a person, or
 - (v) in the case of a drug specified in Part 5 of Schedule 8, for use in mental health or intellectual disability; and
 - (e) the route of administration of the controlled drug prescribed is or is to be, in the case of a drug specified in Schedule 8, the route, or one of the routes, of administration specified in that Schedule opposite that drug.
- (3) Nothing in this Regulation shall be construed as restricting—
- (a) a health service provider from—
 - (i) prohibiting a registered nurse or registered midwife employed by the provider from issuing, in the course of that employment, a prescription for any controlled drug, or any class of controlled drug, for which the nurse or midwife may otherwise issue a prescription pursuant to these Regulations, or
 - (ii) imposing conditions, in addition to those referred to in paragraph (2), which must be satisfied before a registered nurse or registered midwife employed by the provider may, in the course of that employment, issue a prescription pursuant to these Regulations, or
 - (b) the performance of any function conferred on the Nursing and Midwifery Board of Ireland under—
 - (i) the Nurses and Midwives Act 2011 (No. 41 of 2011), or
 - (ii) any other enactment or statutory instrument.

(4) In this Regulation, “health service provider” means the Executive, a hospital, a nursing home, a clinic or any other person whose sole or principal activity or business is the provision of health services, or a class of health services, to the public or a class of the public.

Person may refuse to supply drug if reasonable cause to believe conditions referred to in Regulation 3 have not been satisfied.

4. Without prejudice to the generality of the other provisions of these Regulations pursuant to which a person may refuse to supply a controlled drug, a person may refuse to supply a controlled drug pursuant to a prescription issued by a registered nurse or registered midwife if the person has reasonable cause to believe that the conditions referred to in Regulation 3 have not been satisfied in relation to the practitioner, the controlled drug or the prescription.

PART 3

PRODUCTION, SUPPLY, IMPORTATION AND EXPORTATION OF CONTROLLED DRUGS

General prohibition.

5. (1) Subject to the provisions of these Regulations, a person shall not—
- (a) produce a controlled drug,
 - (b) supply or offer to supply a controlled drug, or
 - (c) import or export a controlled drug.
- (2) (a) Paragraph (1)(b) shall not apply to poppy straw.
- (b) Paragraph (1)(c) shall not apply to any drug specified in—
- (i) Part 2 of Schedule 4, or
 - (ii) Schedule 5.
- (3) (a) Paragraph (1) shall not apply to butan-1,4-diol and dihydrofuran-2(3*H*)-one except where a person imports, exports, produces, supplies or offers to supply either substance in circumstances where he or she knows, or ought reasonably to know, that the substance will be used for the purpose of human ingestion, whether by himself or herself or another person, other than as a flavouring in food.
- (b) In this paragraph references to butan-1,4-diol and dihydrofuran-2(3*H*)-one include—
- (i) any stereoisomeric form of butan-1,4-diol or dihydrofuran-2(3*H*)-one,
 - (ii) any salt of butan-1,4-diol, dihydrofuran-2(3*H*)-one or of a substance specified in clause (i) of this sub-paragraph, and
 - (iii) any preparation or other product containing butan-1,4-diol, dihydrofuran-2(3*H*)-one or a substance specified in clause (i) or (ii) of this paragraph.

Licences.

6. A person so authorised by a licence granted by the Minister under section 14 of the Principal Act (and for the time being in force) may, under and in accordance with the terms of the licence and in compliance with any conditions attached thereto—

- (a) produce, supply, offer to supply, import, export or have in his or her possession any controlled drug to which the licence relates, or
- (b) cultivate opium poppy or Cannabis, or any plant of the genus *Erythroxylon* as may be specified in the licence.

Administration.

7. It shall not be a contravention of the provisions of Regulation 5(1)(b) for—

- (a) any person to administer to another any drug specified in Schedule 5,
- (b) a practitioner, not being a registered veterinary practitioner, to administer to a patient any drug specified in Schedule 2, 3 or 4,
- (c) any person, other than a registered medical practitioner, registered dentist, registered nurse or registered midwife, to administer to a patient, in accordance with the directions of a registered medical practitioner, registered dentist, registered nurse or registered midwife, any drug specified in Schedule 2, 3 or 4.

Exemption for practitioners, pharmacists, etc.

8. (1) Subject to Regulation 3 and paragraph (2), a practitioner or pharmacist may, when acting in his or her capacity as such, for the purpose of his or her profession or business—

- (a) supply or offer to supply any drug specified in Schedule 2, 3, 4 or 5 to any person who may lawfully have that controlled drug in his or her possession, or
- (b) manufacture or compound any such controlled drug.

(2) The reference to practitioner in paragraph (1) shall not include a registered nurse or registered midwife insofar as sub-paragraph (b) of that paragraph is concerned.

(3) A person carrying on a retail pharmacy business may, when acting in his or her capacity as such, for the purpose of his or her profession or business, at the premises at which he or she carries on such business, supply or offer to supply any drug specified in Schedule 2, 3, 4 or 5 to any person who may lawfully have that controlled drug in his or her possession.

Supply.

9. (1) A person may supply or offer to supply any drug specified in Schedule 2, 3, 4 or 5 to any person who may lawfully have that controlled drug in his or her possession where the person so supplying or offering to supply the controlled drug is a person acting in his or her capacity as—

- (a) the director of nursing, director of midwifery or matron of a hospital or nursing home which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions, and the controlled drug is a medicinal product,
- (b) the clinical nurse manager, clinical midwife manager or sister for the time being in charge of a ward, theatre or other department in such a hospital or nursing home where the controlled drug is a medicinal product supplied to him/her by a person responsible for the dispensing and supply of medicines at such hospital or nursing home,

- (c) a person in charge of a laboratory, the recognised activities of which consist of, or include, the conduct of scientific education or research and which is attached to a university or a hospital referred to in subparagraph (a), or a person in charge of any other laboratory engaged in the conduct of scientific education or research and which is attached to any other institution approved for the purpose by the Minister,
- (d) the State Chemist,
- (e) the Director General of Forensic Science Ireland of the Department of Justice and Equality,
- (f) a public analyst appointed under section 10 of the Sale of Food and Drugs Act, 1875,
- (g) the Chief Executive of the Health Products Regulatory Authority,
- (h) a person who is an authorised officer as defined in section 32A of the Irish Medicines Board Act 1995 (No. 29 of 1995) (as inserted by section 17 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)),
- (i) a person employed or engaged in connection with any arrangements made for testing the quality or amount of the drugs, medicines or medical or surgical appliances supplied for the purpose of section 59 of the Health Act 1970, or
- (j) a person appointed as an authorised officer under section 67 of the Pharmacy Act 2007,

provided that nothing in this paragraph shall be construed as authorising—

- (i) the director of nursing, director of midwifery or matron of a hospital or nursing home, having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any controlled drug, or
- (ii) a clinical nurse manager, clinical midwife manager or sister for the time being in charge of a ward, theatre or other department to supply any controlled drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a registered medical practitioner, a registered dentist, a registered nurse or a registered midwife.

(2) A person who is authorised as a member of a group may, under and in accordance with the terms of his or her group authority and in compliance with any conditions attached thereto, supply or offer to supply any drug specified in Schedule 2, 3, 4 or 5 which is a medicinal product to any person who may lawfully have that controlled drug in his or her possession.

(3) The owner of a ship, or the master of a ship which does not carry on board as part of her complement a registered medical practitioner, may supply or offer to supply any drug specified in Schedule 2, 3, 4 or 5 which is a medicinal product—

- (a) to any member of the crew,
- (b) to any person who may lawfully supply that controlled drug, or
- (c) to a member of the Garda Síochána or an officer of customs for the purpose of destruction.

(4) The installation manager of an offshore installation may supply or offer to supply any drug specified in Schedule 2, 3, 4 or 5 which is a medicinal product—

- (a) to any person on that installation, whether present in the course of his or her employment or not,
- (b) to any person who may lawfully supply that controlled drug, or
- (c) to a member of the Garda Síochána or an officer of customs for the purpose of destruction.

(5) A person whose name is for the time being entered in a register kept for the purposes of this paragraph by the Minister under section 14 of the Principal Act may, at the premises in respect of which his or her name is entered in the register and in compliance with any conditions subject to which his or her name is so entered, supply or offer to supply any drug specified in Schedule 3, 4 or 5 to any person who may lawfully have that controlled drug in his or her possession.

PART 4

POSSESSION OF CONTROLLED DRUGS

General exemptions.

10. (1) A person who, by virtue of these Regulations, is authorised to produce, supply or offer to supply any drug specified in Schedule 2, 3 or 4 may in accordance with the provisions of these Regulations have such controlled drug in his or her possession.

(2) A person may have in his or her possession any drug specified in Schedule 2 or 3, or Part 1 of Schedule 4, for administration for medical, dental or veterinary purposes in accordance with the directions of a practitioner; provided that this paragraph shall not have effect in the case of a person to whom the controlled drug has been supplied by or on the prescription of a registered medical practitioner, registered dentist, registered nurse or registered midwife if—

- (a) that person was then being supplied with any controlled drug by or on the prescription of another registered medical practitioner, registered dentist, registered nurse or registered midwife and failed to disclose

that fact to the first-mentioned registered medical practitioner, registered dentist, registered nurse or registered midwife, as the case may be, before the supply by him or her or on his or her prescription, or

- (b) that person or any other person on his/her behalf made a declaration or statement which was false in any particular for the purpose of obtaining the supply or prescription.

(3) A person whose name is for the time being entered in a register kept for the purposes of this paragraph by the Minister under section 14 of the Principal Act may, in compliance with any conditions subject to which his or her name is so entered, have in his or her possession any drug specified in Schedule 3 or 4.

(4) The master of a foreign ship which is in a port in the State may have in his or her possession any drug specified in Schedule 2 or 3, or Part 1 of Schedule 4, so far as is necessary for the equipment of his or her ship.

(5) A person who is authorised as a member of a group may, under and in accordance with his or her group authority and in compliance with any conditions attached thereto, have any drug specified in Schedule 2 or 3, or Part 1 of Schedule 4, which is a preparation in his or her possession.

Exemption to possess butan-1,4-diol or dihydrofuran-2(3H)-one.

11. (1) A person may have in his or her possession butan-1,4-diol or dihydrofuran-2(3H)-one except where he knows or ought reasonably to know that such substance is intended for human ingestion, whether by himself or herself or another person, other than as a flavouring in food.

(2) In this Regulation references to butan-1,4-diol and dihydrofuran-2(3H)-one include—

- (a) any stereoisomeric form of butan-1,4-diol or dihydrofuran-2(3H)-one,
- (b) any salt of butan-1,4-diol, dihydrofuran-2(3H)-one or of a substance specified in subparagraph (a), and
- (c) any preparation or other product containing butan-1,4-diol, dihydrofuran-2(3H)-one or a substance specified in sub-paragraph (a) or (b).

Exemption for midwives in respect of pentazocine and pethidine.

12. (1) Subject to the provisions of this Regulation, a midwife who is employed by the Executive or a hospital authority to provide community-based maternity services, or a self-employed community-based midwife providing maternity services who has notified to the Executive his or her intention to practise, may, so far as is necessary for his or her practice as a midwife, have in his or her possession or administer any medicinal product which contains pentazocine or pethidine.

(2) Nothing in paragraph (1) shall be construed as authorising a registered midwife to have pentazocine or pethidine in his or her possession unless it has been obtained—

- (a) on foot of a written order—
 - (i) signed by—
 - (I) the registered midwife, and
 - (II) a registered medical practitioner, a registered nurse, or registered midwife who falls within the definition of “practitioner” in Regulation 2, practising in the area in which the registered midwife practises, stating his or her registration number, and
 - (ii) setting out the name, address and registration number of the registered midwife, the name of the controlled drug, the purpose for which it is required and the quantity to be obtained, or
- (b) if the registered midwife falls within the definition of “practitioner” in Regulation 2, without prejudice to the generality of subparagraph (a), on foot of a written order signed by the registered midwife setting out the name and address of the registered midwife, his or her registration number, the name of the controlled drug, the purpose for which it is required and the quantity to be obtained.

General authorities.

13. (1) Any of the following persons may have a controlled drug in his or her possession:

- (a) a member of the Garda Síochána when acting in the course of his or her duty as such;
- (b) a prison officer when acting in the course of his or her duty as such;
- (c) an officer of customs when acting in the course of his or her duty as such;
- (d) a person authorised in writing in accordance with section 24 of the Principal Act (as amended by section 9 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006), when acting in the course of his or her duty as such;
- (e) a person engaged in connection with the Postal Services provided by An Post when acting in the course of his or her duty as a person so engaged;
- (f) a person engaged in the work of any laboratory to which the controlled drug has been sent for forensic examination when acting in the course of his or her duty as a person so engaged;
- (g) a registered nurse engaged in providing palliative care when acting in the course of the nurse’s duty as a nurse so engaged;

- (h) a person engaged in the business of a carrier when acting *bona fide* in the course of that business;
 - (i) a person engaged in conveying the controlled drug to a person authorised by these Regulations to have it in his or her possession;
 - (j) an official of the Department of Agriculture, Food and the Marine, engaged, in his or her official capacity as such, in the work of sampling for analysis of crops of *Cannabis sativa L*, for the purpose of Commission Implementing Regulation (EU) No. 809/2014 of 17 July 2014⁵;

(2) A person who is lawfully in possession of a controlled drug may supply that drug to a person from whom he or she obtained it.

(3) A person who is lawfully in possession of a drug specified in Schedule 2, 3, 4 or 5 which has been supplied by or on the prescription of a registered medical practitioner, registered dentist, registered nurse or registered midwife for the treatment of that person, or of a person whom he or she represents, may supply that drug for the purposes of destruction to a person carrying out a retail pharmacy business.

(4) A person who is lawfully in possession of a drug specified in Schedule 2, 3, 4 or 5 which has been supplied by or on the prescription of a registered veterinary practitioner for the treatment of animals, may supply that drug for the purposes of destruction to a registered veterinary practitioner, or to a person carrying out a retail pharmacy business.

PART 5

DOCUMENTATION AND RECORD-KEEPING

Documents to be obtained by a supplier.

14. (1) Where a person (“the supplier”), not being a practitioner, supplies a controlled drug otherwise than on a prescription, he or she shall not deliver the drug to a person who—

- (a) purports to be sent by or on behalf of the person to whom it is to be supplied (“the recipient”), and
- (b) is not authorised by any provision of these Regulations other than the provisions of Regulation 13(1)(i) to have that controlled drug in his or her possession,

unless the person produces to the supplier a statement in writing signed by the recipient to the effect that the person is empowered by the recipient to receive that controlled drug on his or her behalf, and the supplier is reasonably satisfied that the document is a genuine document.

⁵OJ No. L. 227, 31.7.2014, p. 69.

(2) Where a person (“the supplier”) supplies a controlled drug, otherwise than on a prescription or by way of administration, to any of the persons specified in paragraph (4), the supplier shall not deliver the drug—

- (a) until he or she has obtained a requisition in writing which—
 - (i) is signed and dated by the person to whom the controlled drug is to be supplied (“the recipient”),
 - (ii) states the name, address, occupation and, where applicable, registration number of the recipient,
 - (iii) specifies the name of the controlled drug, the purpose for which the drug to be supplied is required and the total quantity to be supplied, and
 - (iv) where appropriate, satisfies the requirements of paragraph (5), and
- (b) unless he or she is reasonably satisfied that the signature on the requisition referred to at subparagraph (a) is that of the recipient and that the recipient is engaged in the occupation specified in the requisition,

provided that where the recipient is a practitioner and he or she represents that he or she urgently requires a controlled drug for the purpose of his or her profession, the supplier may, if he or she is reasonably satisfied that the recipient so requires the drug and is unable by reason of urgency to furnish such requisition, deliver the drug to the recipient on an undertaking by the recipient to furnish such a requisition within 24 hours of such delivery.

(3) A practitioner who has given an undertaking in accordance with paragraph (2) shall deliver to the person by whom the controlled drug was supplied a signed requisition in accordance with the undertaking.

(4) The persons referred to in paragraph (2) are—

- (a) a practitioner;
- (b) the director of nursing, director of midwifery or matron of a hospital or nursing home;
- (c) a person in charge of a laboratory;
- (d) the owner of a ship, or the master of a ship which does not carry a registered medical practitioner on board as part of her complement;
- (e) the master of a foreign ship in a port in the State;
- (f) the installation manager of an offshore installation.

(5) A requisition furnished for the purpose of paragraph (2) shall—

- (a) where it is furnished by the director of nursing, director of midwifery or matron of a hospital or nursing home, be signed by a practitioner employed or engaged in that hospital or nursing home,
- (b) where it is furnished by the master of a foreign ship, contain a statement, signed by a medical officer of the Executive, that the quantity of the controlled drug to be supplied is the quantity necessary for the equipment of the ship, or
- (c) where it is furnished by the installation manager of an offshore installation, contain a statement signed by the Industrial Medical Adviser (Offshore Installations) that the quantity of the controlled drug to be supplied is the quantity necessary for the equipment of that installation.

(6) Subject to paragraph (9), where the person responsible for the dispensing and supply of medicines at any hospital or nursing home supplies a controlled drug to a clinical nurse manager, clinical midwife manager or sister for the time being in charge of a ward, theatre or other department in that hospital or nursing home, he or she shall—

- (a) obtain a requisition in writing, signed by the clinical nurse manager, clinical midwife manager or sister which specifies the name of the controlled drug and total quantity to be supplied, and
- (b) mark the requisition in such manner as to show that it has been complied with,

and any requisition obtained for the purposes of this paragraph shall be retained in the dispensary at which the controlled drug was supplied and a copy of the requisition or a note of it shall be retained or kept by the clinical nurse manager, clinical midwife manager or sister for the time being in charge of that ward, theatre or other department.

(7) A person who supplies a controlled drug to—

- (a) a person carrying on a retail pharmacy business,
- (b) a pharmacist responsible for the dispensing and supply of medicines in a hospital or nursing home, or
- (c) the director of nursing, director of midwifery or matron of a hospital or nursing home,

shall furnish with each consignment of such controlled drug a form of receipt.

(8) The pharmacist or, as the case may be, the director of nursing, director of midwifery or matron on receipt of controlled drugs in the manner provided for in paragraph (7) shall—

- (a) check the statements on the form of receipt,

- (b) enter thereon any deviations observed in the drugs received,
- (c) enter the date of receipt of the drugs,
- (d) sign the receipt document with his or her usual signature, and
- (e) return the receipt to the supplier not later than 3 working days from the date of receipt of the said drugs.

(9) Paragraph (6) shall not apply in the case of the dispensing and supply of any drug specified in Part 1 of Schedule 4.

(10) Nothing in this Regulation shall have effect in relation to—

- (a) any drug specified in Part 2 of Schedule 4,
- (b) any drug specified in Schedule 5, or
- (c) poppy straw.

Form of prescriptions.

15. (1) Subject to the provisions of this Regulation, a practitioner shall not issue a prescription for a controlled drug, other than a drug specified in Part 2 of Schedule 4 or in Schedule 5, unless—

- (a) he or she is satisfied as to the identity of the person for whose treatment the prescription is to be issued, or in the case of a prescription issued by a registered veterinary practitioner, the identity of the person to whom the controlled drug is to be delivered, and
- (b) the prescription complies with the requirements specified in paragraph (2).

(2) The requirements referred to in paragraph (1) are as follows:

- (a) the prescription shall be in ink or otherwise so as to be indelible;
- (b) the prescription shall clearly indicate the full name (including the first name) of the practitioner issuing it and state whether he or she is a registered medical practitioner, registered dentist, registered veterinary practitioner, registered nurse or registered midwife and state his or her registration number;
- (c) the prescription shall be signed by the practitioner issuing it with his or her usual signature and be dated by him or her;
- (d) except in the case of a health prescription, the prescription shall specify the address of the practitioner issuing it;
- (e) subject to paragraph (3), the prescription shall specify the telephone number at which the practitioner issuing it may be contacted;

- (f) subject to paragraph (3), the prescription shall specify the name (including the first name), and address of the person for whose treatment it is issued or, in the case of a prescription issued by a registered veterinary practitioner, the name (including the first name) and address of the person to whom the controlled drug prescribed is to be delivered;
- (g) subject to paragraph (4), the prescription shall specify in the practitioner's handwriting—
 - (i) the name of the controlled drug to be prescribed,
 - (ii) the dose of the controlled drug to be taken by the person or animal for whose treatment the prescription is issued,
 - (iii) in the case of a prescription for a controlled drug which is a preparation—
 - (I) the form and, where appropriate, the strength of the controlled drug to be supplied, and
 - (II) either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied, and
 - (iv) in the case of a prescription for a controlled drug which is not a preparation, the total quantity (in both words and figures) of the controlled drug to be supplied;
- (h) in the case of a prescription for a total quantity intended to be dispensed in instalments, the number of instalments and the intervals at which the instalments may be dispensed.

(3) In the case of a prescription issued for the treatment of a patient in a hospital or nursing home, it shall be a sufficient compliance with paragraph (2)(e) and (f) if the prescription is written on the patient's bed card or patient's medication record and such card or record shall be sufficient evidence of identity for the purposes of paragraph (1)(a).

(4) The requirements specified in paragraph (2)(g) shall not be required to be in the practitioner's own handwriting in the case of a prescription for a controlled drug specified in—

- (a) Part 1 of Schedule 4, or
- (b) the Schedule to the Misuse of Drugs (Supply of Methadone) Regulations 1998 (S.I. No 225 of 1998).

Supply on prescription.

16. (1) Subject to paragraph (6), a person shall not supply a controlled drug, other than a drug specified in Part 2 of Schedule 4 or in Schedule 5, on a prescription—

- (a) unless the prescription complies with the provisions of Regulation 15,
- (b) unless the address specified in the prescription as the address of the practitioner issuing it is an address within the State,
- (c) unless he or she either is acquainted with the signature of the practitioner by whom it purports to be issued and has no reason to believe that the signature is not genuine, or has taken reasonably sufficient steps to satisfy himself or herself that it is genuine,
- (d) before the date specified in the prescription,
- (e) subject to paragraph (3)—
 - (i) later than 14 days after the date of the prescription, or
 - (ii) where the prescription contains a direction that specified instalments of the total quantity may be dispensed at stated intervals—
 - (I) in the case of the first instalment, later than 14 days after the date specified in the prescription, and
 - (II) in the case of subsequent instalment, later than two months after the date specified in the prescription,
- (f) unless he or she is satisfied—
 - (i) as to the identity of the person for whose treatment the prescription is issued, or in the case of a prescription issued by a registered veterinary practitioner, the identity of the person to whom the controlled drug is to be delivered, and
 - (ii) in the case of the supply being made to a representative of the said person, that the said representative is a *bona fide* representative of the said person.

(2) Subject to paragraph (4), a person supplying on a prescription a controlled drug, other than a drug specified in Schedule 4 or 5 shall, at the time of the supply—

- (a) mark on the prescription the date on which the drug is supplied, and
- (b) retain the prescription on the premises from which the drug was supplied.

(3) In the case of the supply on prescription of a controlled drug specified in Part 1 of Schedule 4—

- (a) the person supplying the drug shall comply with the relevant provisions of paragraphs (2) and (5) of Regulation 7 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), as amended from time to time,
- (b) paragraph (1)(e) shall not apply,
- (c) where the prescription is one which has been endorsed by the practitioner as one which may be dispensed on more than one occasion, and where the prescription is dispensed in part, the person who dispensed the prescription shall—
 - (i) forthwith record on the prescription—
 - (I) the quantity of each controlled drug supplied by him or her,
 - (II) the date on which he or she supplied such quantity, and
 - (III) his or her name and address, and
 - (ii) retain a copy of the prescription, including a copy of any record made under clause (i), on the premises from which the drug was supplied, and
- (d) where the dispensing of the controlled drug has been completed, the person who dispensed it shall—
 - (i) forthwith write or print prominently on the prescription the word “dispensed” and the date on which it was dispensed, and
 - (ii) subject to paragraph (4), retain the prescription on the premises from which the drug was supplied.

(4) Paragraphs (2) and (3)(d)(ii) shall apply to a health prescription on the basis that the duplicate copy thereof, made by the practitioner at the time of writing the original, shall be treated for the purposes of this Regulation as if it were the original document.

(5) In the case of a controlled drug specified in the Schedule to the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998, supplied on prescription in prison—

- (a) paragraph (2)(a) shall not apply, and
- (b) subject to Regulation 22(6), a hard-copy record shall be made, at the time of administration of the controlled drug, of—
 - (i) the name and identity number of the patient to whom the controlled drug is administered,
 - (ii) the name of the person who issued the prescription and the date on which the prescription was issued for that patient,

- (iii) the name, dose, form and quantity of the controlled drug prescribed,
- (iv) the name, dose, form and quantity of the controlled drug administered to the patient, and
- (v) the date on which the controlled drug is administered to the patient.

(6) Nothing in this Regulation shall prohibit the operation of the provisions relating to the duties of pharmacists in relation to prescriptions for interchangeable medicinal products under a branded name set out in Chapter 2 of Part 2 of the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013).

Marking of containers.

17. (1) Subject to paragraph (2), a person shall not supply a controlled drug otherwise than in a bottle, package or other container which—

- (a) in the case of a controlled drug other than a preparation, is clearly marked with the name of the drug and the amount of the drug contained therein,
- (b) in the case of a controlled drug which is a preparation made up into tablets, capsules or other dosage units, is clearly marked with the name of the drug, the amount of each component (being a controlled drug) of the preparation in each dosage unit and the number of dosage units in the bottle, package or other container, and
- (c) in the case of a controlled drug which is a preparation not so made up, is clearly marked with the name of the drug, the total amount of the preparation in the bottle, package or other container and the percentage of each of its components which is a controlled drug.

(2) Nothing in this Regulation shall have effect in relation to—

- (a) a drug specified in Part 2 of Schedule 4,
- (b) a drug specified in Schedule 5,
- (c) poppy straw, or
- (d) the supply of a controlled drug by or on the prescription of a practitioner.

Documents required for export of controlled drugs.

18. (1) A person shall not export a controlled drug unless the transactions relating thereto are properly documented and the commercial documents such as invoices, cargo manifests, customs, transport and other shipping documentation accompanying the drug include the name of the controlled drug as set out in the relevant Schedule or, where such name would not adequately

identify the drug, the international non-proprietary name for the drug as recommended by the World Health Organisation.

(2) The documentation referred to in paragraph (1) shall be dated and shall also include the total quantity being exported, the name and address of the exporter and of the importer and, when available, that of the ultimate consignee.

Keeping of registers for drugs in Schedules 1 and 2.

19. (1) Subject to paragraph (4) and Regulation 20, every person authorised by or under Regulation 6, 8 or 9 to supply any drug specified in Schedule 1 or 2 shall comply with the following requirements:

- (a) he or she shall, in accordance with the provisions of this Regulation, keep a register and shall enter therein in chronological sequence and in a manner which will show a running stock balance, particulars of every quantity of such a drug obtained by him or her and of every quantity of such a drug supplied whether by way of administration or otherwise by him or her whether to persons within or outside the State;
- (b) he or she shall use a separate register or separate part of a register for entries made in respect of each class of drug; and
- (c) the entries in the register referred to in subparagraph (a) shall be—
 - (i) in the form specified in Schedule 6, or
 - (ii) as the case may require, in the form specified in Part 1 or Part 2 of Schedule 7.

(2) For the purposes of paragraph (1)(b), each of the drugs specified in paragraphs 1 and 3 of Schedule 1 and paragraphs 1, 3 and 6 of Schedule 2 (together with its salts) and any preparation or other product containing it or any of its salts shall be treated as a separate class and any stereoisomeric form of a controlled drug or its salts shall be treated as being in the same class as that drug.

(3) Nothing in paragraph (1) shall be taken as preventing the use of a separate section within a register or a separate part of a register in respect of different controlled drugs or strengths of controlled drugs comprised within the class of controlled drugs to which that register or separate part relates.

(4) The foregoing provisions of this Regulation shall not have effect in relation to—

- (a) a person licensed under section 14 of the Principal Act to supply any controlled drug, where the licence so directs, or
- (b) the clinical nurse manager or clinical midwife manager or sister for the time being in charge of a ward, theatre or other department in a hospital or nursing home.

- (5) Any person required to keep a register under this Regulation shall comply with the following requirements:
- (a) the class of controlled drugs to which the entries on any page of any such register relate shall be specified at the head of that page;
 - (b) every entry required to be made under this Regulation in a register shall, where it is reasonably practicable to do so, be made on the day on which the controlled drug is obtained or on which the transaction in respect of the supply of the controlled drug by the person required to make the entry takes place or, in any case, on the day next following that day;
 - (c) no cancellation, obliteration or alteration of any such entry shall be made, and a correction of such an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made;
 - (d) every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible;
 - (e) a register shall not be used for any purpose other than the purposes of these Regulations;
 - (f) subject to subparagraph (g), not more than one register shall be kept at one time in respect of each class of controlled drug in respect of which he or she is required to keep a separate register;
 - (g) a separate register shall be kept in respect of each premises at which the person required to keep the register carries on his or her business or occupation and where the business is carried on in separate departments within a premises a separate register may, with the approval of the Minister, be kept in respect of each such department; and
 - (h) every such register in which entries are currently being made shall be kept at the premises to which it relates and shall be readily available for inspection under section 24 of the Principal Act.
- Record-keeping in particular cases for drugs in Schedule 2.*
20. (1) Where a drug specified in Schedule 2 is supplied in accordance with Regulation 9(3)(a) to a member of the crew of a ship, an entry in the official log book required to be kept under the Acts relating to merchant shipping, or in the case of a ship which is not required to carry such an official log book, a report signed by the master of the ship, shall, notwithstanding anything in these Regulations, be a sufficient record of the supply if the entry or report specifies the controlled drug supplied and, in the case of a report, it is delivered as soon as may be to the superintendent of a mercantile marine office established and maintained under the Acts relating to merchant shipping.
- (2) Where a drug specified in Schedule 2 is supplied in accordance with Regulation 9(4)(a) to a person on an offshore installation, an entry in the installation

log book which specifies the controlled drug supplied shall, notwithstanding anything in these Regulations, be a sufficient record of the supply.

(3) A midwife authorised under Regulation 12 to have pethidine in his or her possession shall—

- (a) on each occasion on which he or she obtains a supply of pethidine, enter in a book kept by him or her and used solely for the purposes of this paragraph the date, the name and address of the person from whom the drug was obtained, the amount obtained and the form in which it was obtained, and
- (b) on administering pethidine to a patient, enter in the said book as soon as practicable the name and address of the patient, the amount administered and the form in which it was administered.

Keeping of records for drugs in Schedules 3 and 4.

21. (1) A person who is authorised by a licence granted by the Minister under section 14 of the Principal Act to produce any drug specified in Schedule 3 or 4 shall make a record of each quantity of such a controlled drug produced by him or her.

(2) A person who is authorised by a licence granted by the Minister under section 14 of the Principal Act to import or export any drug specified in Schedule 3 or Part 1 of Schedule 4 shall make a record of each quantity of such controlled drug imported or exported by him or her.

(3) A person who is authorised under Regulation 9(5) to supply any drug specified in Part 2 of Schedule 4 shall make a record of each quantity of such controlled drug imported or exported by him or her.

Preservation of registers, etc.

22. (1) All registers and books kept in pursuance of Regulation 19 or 20(3) shall be preserved for a period of two years from the date on which the last entry therein is made.

(2) Every order, prescription or requisition on which a controlled drug is supplied in pursuance of these Regulations shall be preserved for a period of two years from the date on which the last supply of a controlled drug was made on such order, prescription or requisition.

(3) Paragraph (2) shall apply to a health prescription or, as the case may be, to a health service requisition on the basis that the keeping of the duplicate copy thereof, made by the practitioner at the time of writing the original, shall be treated as if it were the keeping of the original document.

(4) Every receipt made and returned in pursuance of Regulation 14(7) and (8) shall be preserved for a period of two years from the date entered on the document as the date of receipt of the controlled drugs to which the document relates.

(5) Every record made in pursuance of Regulation 21 shall be preserved for a period of two years from the date on which the record was made.

(6) Every record made in pursuance of Regulation 16(5) shall be preserved in the prison for a period of two years from the date on which the controlled drug was administered to the patient.

(7) Every copy of a prescription made in pursuance of Regulation 16(3)(c)(ii) shall be preserved for a period of 2 years from the date on which the supply of the controlled drug was made.

Preservation of records for drugs in Schedule 3, Part 1 of Schedule 4, and Schedule 5.

23. (1) A producer of any drug specified in Schedule 3, Part 1 of Schedule 4, or Schedule 5, and a wholesaler of any such drug, shall keep every invoice or other like record issued in respect of each quantity of such drug obtained or produced by him or her and in respect of each quantity of such drug supplied by him or her.

(2) A person who is authorised under Regulation 9(5) to supply any drug specified in Schedule 3 or Part 1 of Schedule 4 shall keep every invoice or other like record issued in respect of each quantity of such drug obtained by him or her and in respect of each quantity of such drug supplied by him or her.

(3) A director of nursing, director of midwifery or matron of a hospital or nursing home or, as the case may be, a pharmacist responsible for the dispensing and supply of medicines in such hospital or nursing home and a person in charge of a laboratory shall, in respect of any drug specified in Schedule 3 or Part 1 of Schedule 4, keep every invoice or other like record issued in respect of each quantity of such drug obtained by him or her and in respect of each quantity of such drug supplied by him or her.

(4) A person carrying on a retail pharmacy business shall—

(a) in the case of any drug specified in Schedule 3 or Part 1 of Schedule 4, keep every invoice or other like record issued in respect of each quantity of such drug obtained by him or her and in respect of each quantity of such drug supplied by him or her, and

(b) in the case of any drug specified in Schedule 5, keep every invoice or other like record issued in respect of each quantity of such drug obtained by him or her.

(5) Every invoice or other record which is required by this Regulation to be kept in respect of a drug specified in Schedule 3 or Part 1 of Schedule 4 shall contain information sufficient to identify the date of the transaction and in the case of a drug obtained, the person by whom such drug was supplied and in the case of a drug supplied, the person to whom such drug was supplied.

(6) Every document kept in pursuance of this Regulation shall be preserved for a period of two years from the date on which it was issued provided that the

keeping of a copy of the document made at any time during the said period of two years shall be treated for the purposes of this Regulation as if it were the keeping of the original document.

Furnishing of information with respect to controlled drugs.

24. (1) Subject to paragraph (4), the persons referred to in paragraph (3) shall, on demand made by the Minister or by any person authorised in writing by the Minister in that behalf—

- (a) furnish such particulars as may be requested in respect of the producing, obtaining or supplying by him or her of any controlled drug or in respect of any stock of such drugs in his or her possession,
- (b) for the purpose of confirming any such particulars, produce any stock of such drugs in his or her possession, and
- (c) produce any register, book or document in his or her possession which is required to be kept under these Regulations in respect of any dealings in controlled drugs.

(2) Where the demand referred to in paragraph (1) is made in writing the particulars, or confirmation thereof, shall be furnished not later than fourteen days from the date of the said demand.

(3) The persons referred to in paragraph (1) are—

- (a) any person authorised by or under these Regulations or by a licence granted under section 14 of the Principal Act, to produce, import or export any controlled drug,
- (b) a wholesaler,
- (c) a person carrying on a retail pharmacy business,
- (d) a practitioner,
- (e) the director of nursing, director of midwifery or matron of a hospital or nursing home or, as the case may be, the pharmacist responsible for the dispensing and supply of medicines in such hospital or nursing home,
- (f) a person in charge of a laboratory, and
- (g) a person who is authorised under Regulation 9(5) to supply any controlled drug.

(4) Nothing in this Regulation shall require the furnishing of personal records which a person has acquired or created in the course of his or her profession or occupation and which he or she holds in confidence.

(5) In paragraph (4), “personal records” means documentary or other records concerning an individual (whether living or dead) who can be identified from

them and relating to his or her physical or mental health, but does not include any register, book, prescription or other document required to be kept under these Regulations relating to any dealings in controlled drugs.

PART 6

MISCELLANEOUS

Destruction of certain drugs.

25. (1) A person who is required by any provision of these Regulations, or by any term or condition of a licence granted under section 14 of the Principal Act to keep records with respect to a drug specified in Schedule 1, 2, 3 or 4, shall not destroy such drug or cause such drug to be destroyed except in the presence of and in accordance with any directions given by a person authorised (whether personally or as a member of a class) for the purposes of this paragraph by the Minister (in this Regulation referred to as an “authorised person”).

(2) An authorised person may, for the purpose of analysis, take a sample of a drug specified in Schedule 1, 2, 3 or 4 which is to be destroyed.

(3) Where a drug specified in Schedule 1, 2, 3 or 4 is destroyed in pursuance of paragraph (1) by or at the instance of a person who is required by any provision of these Regulations, or by any term or condition of a licence having effect under section 14 of the Principal Act, to keep a record in respect of the obtaining or supply of that drug, that record shall include particulars of the date of destruction and the name of the controlled drug and the quantity destroyed and shall be signed by the authorised person in whose presence the controlled drug is destroyed.

(4) Where the master or owner of a ship or installation manager of an off-shore installation has in his or her possession a drug specified in Schedule 2 which he or she no longer requires, he or she shall not destroy the drug or cause it to be destroyed but shall give it to a member of the Garda Síochána, an officer of customs or a person who may lawfully supply that controlled drug to him or her.

(5) Nothing in paragraph (1) or (3) shall apply to any person who is required to keep records only by virtue of Regulation 21(2) or (3) or Regulation 23(3) or (4)(a).

Disposal of certain drugs on cessation of business.

26. A person carrying on a retail pharmacy business who ceases to carry on a retail pharmacy business shall, on demand made by a person authorised in writing in that behalf by the Minister, the Health Products Regulatory Authority or the Council of the Pharmaceutical Society of Ireland, in respect of that retail pharmacy business—

- (a) furnish such particulars as may be requested in respect of any stock of a controlled drug in his or her possession,

- (b) for the purpose of confirming any such particulars, produce any stock of such drugs in his or her possession,
- (c) produce the register and such other books or documents in his or her possession relating to any dealings in drugs specified in Schedule 2, 3 or 4 as may be requested, and
- (d) dispose of any stock of such drugs in his or her possession in accordance with any directions given by the Minister or by a person authorised as aforesaid.

Forged, etc. prescriptions.

27. Section 18(3) of the Principal Act (which prohibits the possession of either a forged prescription or a duly issued prescription which has been altered with intent to deceive) shall not apply in relation to any of the following persons:

- (a) a member of the Garda Síochána when acting in the course of his or her duty as such;
- (b) a person who is an authorised officer as defined in section 32A of the Irish Medicines Board Act 1995 (inserted by section 17 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006), when acting in the course of his or her duty as such;
- (c) a person appointed as an authorised officer under section 67 of the Pharmacy Act 2007, when acting in the course of his or her duty as such;
- (d) a person authorised in writing by the Minister or by the Health Products Regulatory Authority in accordance with section 24 of the Principal Act (as amended by section 9 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006), when acting in his or her capacity as such;
- (e) a person appointed as the secretary to, or member of, a committee of inquiry established under section 8 of the Principal Act (as amended by section 3 of the Misuse of Drugs Act 1984 (No. 18 of 1984)), when acting in the course of his or her duty as such;
- (f) a person who has taken into his or her possession a forged prescription or a duly issued prescription which has been altered with intent to deceive, for the purpose of—
 - (i) preventing another from committing or continuing to commit an offence under the Principal Act, or
 - (ii) delivering it into the custody of a person specified in paragraph (a), (b), (c) or (d) of this Regulation.

Publication, sale, etc. of certain books, periodicals and other publications.

28. The drugs specified in Schedule 1 are hereby prescribed for the purposes of section 5 of the Misuse of Drugs Act 1984.

References to revoked Regulations of 1988 in other enactments.

29. (1) A reference in any other enactment to the Regulations of 1988 shall be construed as a reference to these Regulations.

(2) A reference in any other enactment to a provision of the Regulations of 1988 listed in column 1 of Schedule 9 shall be construed as a reference to the corresponding provision of these Regulations listed in column 3 of Schedule 9.

Transitional provisions.

30. (1) Notwithstanding Regulations 22 and 23, any register, book, prescription or other document required to be preserved under Regulation 19 or 20 of the Regulations of 1988 shall be preserved for the period of time required under the relevant provision of those Regulations as if those Regulations had not been revoked.

(2) Notwithstanding Regulation 16, it shall not be a contravention of these Regulations for a person to supply a controlled drug specified in Part 1 of Schedule 4 on foot of a prescription which does not comply with Regulation 16(1) if—

- (a) the prescription was issued before the coming into operation of these Regulations,
- (b) the prescription complies with the requirements of Regulations 7(1) or 7A(1) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended and inserted by Regulations 4 and 5 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014) respectively), as appropriate, or, in the case of an animal remedy, Regulation 43 of the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) (as amended by Regulation 2(c) and (d) of the European Communities (Animal Remedies) (Amendment) Regulations 2014 (S.I. No. 162 of 2014)), and
- (c) the supply is made not later than the date specified in Regulation 7(5)(a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 or, in the case of an animal remedy, the date specified in Regulation 43(7)(c) of the European Communities (Animal Remedies) (No. 2) Regulations 2007.

(3) Notwithstanding Regulations 15 and 16, a prescription for a controlled drug specified in Schedule 2 or 3, written and issued before the commencement of these Regulations in accordance with Regulation 13 of the Regulations of 1988, shall be deemed to be written and issued in accordance with Regulation 15 for the purpose of supply in accordance with Regulation 16 of these Regulations.

SCHEDULE 1

1. The following substances and products, namely:—

- (a) *N*-(Adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide
(otherwise known as Clockwork Orange, 5F AKB48)
- 5-(2-Aminopropyl)indole (otherwise known as 5-IT)
- 1-(1,3-Benzodioxol-5-yl)-2-(1-pyrrolidinyl)-1-pentanone
- N*-(1-Benzyl-4-piperidyl)propionanilide
- 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-[(2-methoxyphenyl)methyl]ethanamine (otherwise known as 25B-NBOMe)
- 1-(4-Bromofuro[2,3-*f*][1]benzofuran-8-yl)propan-2-amine (otherwise known as BromodragonFLY)
- Bufotenine
- Cannabinol, except where contained in Cannabis or cannabis resin
- Cannabinol derivatives
- Cannabis (not being a preparation specified in paragraph 5 of Schedule 4 Part 1)
- Cannabis resin
- Cathinone
- 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-[(2-methoxyphenyl)methyl]ethanamine (otherwise known as 25C-NBOMe)
- 1-Cyclohexyl-4-(1,2-diphenylethyl)piperazine (otherwise known as MT-45)
- Coca leaf
- Concentrate of poppy straw
- 3,4-Dichloro-*N*-[[1-(dimethylamino)cyclohexyl]methyl]benzamide
(otherwise known as AH-7921)
- [2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-*de*]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone
- N,N*-Diethyltryptamine
- 2,5-Dimethoxy- α ,4-dimethylphenethylamine
- N,N*-Dimethyltryptamine

3-Dimethylheptyl-11-hydroxyhexahydrocannabinol

Eticyclidine

Etryptamine

1-(2-Fluorophenyl)-2-methylaminopropan-1-one

1-(3-Fluorophenyl)-2-methylaminopropan-1-one

1-(4-Fluorophenyl)-2-methylaminopropan-1-one

9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[*c*]chromen-1-ol

[9-Hydroxy-6-methyl-3-[5-phenylpentan-2-yl]oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin-1-yl]acetate

N-Hydroxy-tenamphetamine

2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-[(2-methoxyphenyl)methyl]ethanamine (otherwise known as 25I-NBOMe)

Khat (being the leaves of *Catha edulis* (Celastraceae))

Lysergamide

Lysergide and other *N*-alkyl derivatives of lysergamide

Mescaline

Methcathinone

2-(3-Methoxyphenyl)-2-(ethylamino)cyclohexanone (otherwise known as methoxetamine)

1-(4-Methoxyphenyl)-2-(methylamino)propan-1-one

Methyl (2*S*,4*aR*,6*aR*,7*R*,10*aS*,10*bR*)-9-acetyloxy-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxo-2,4a,5,6,7,8,9,10a-octahydro-1*H*-benzo[*f*]isochromene-7-carboxylate (otherwise known as Salvinorin A) and any product, whether natural or otherwise, including any plant or plant material of any kind or description, which contains any proportion of the said substance

2-Methylamino-1-(3,4-methylenedioxyphenyl)butan-1-one

2-Methylamino-1-(3,4-methylenedioxyphenyl)propan-1-one

4-Methyl-aminorex

Methyl 2-[[1-(cyclohexylmethyl)indole-3-carbonyl]amino]-3,3-dimethylbutanoate (otherwise known as MDMB CHMICA)

Methyl (*E*)-2-[(2*S*,3*S*,7*aS*,12*bS*)-3-ethyl-7*a*-hydroxy-8-methoxy-2,3,4,6,7,12*b*-hexahydro-1*H*-indolo[2,3*a*]quinolizin-2-yl]-3-methoxyprop-2-enoate (otherwise known as 7-Hydroxymitragynine) and any product, whether natural or otherwise, including any plant or plant material of any kind or description, which contains any proportion of the said substance

Methyl (*E*)-2-[(2*S*,3*S*,12*bS*)-3-ethyl-8-methoxy-1,2,3,4,6,7,12,12*b*-octahydroindolo[2,3*a*]quinolizin-2-yl]-3-methoxyprop-2-enoate (otherwise known as Mitragynine) and any product, whether natural or otherwise, including any plant or plant material of any kind or description, which contains any proportion of the said substance

4-Methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (otherwise known as 4,4'-DMAR)

α -Methyl-4-(methylthio)phenethylamine

1-(4-Methylphenyl)-2-methylaminopropan-1-one

Psilocin

Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (otherwise known as Clockwork Orange, PB22)

Raw opium

Rolicyclidine

Tenocyclidine

N-[1-(2-Thenyl)-4-piperidyl]propionanilide

- (b) Any substance (not being bupropion, diethylpropion or pyrovalerone) structurally derived from 2-amino-1-phenyl-1-propanone by modification in any of the following ways:
- (i) by substitution in the phenyl ring to any extent with alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylenedioxy, haloalkyl or halo substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents;
 - (ii) by substitution at the 2- or 3-position of the propanone side-chain with an alkyl substituent;
 - (iii) by substitution at the nitrogen atom with one or more alkyl or dialkyl groups, or by inclusion of the nitrogen atom in a cyclic structure.
- (c) Any substance structurally derived from 2-amino-1-propanone by substitution at the 1-position with any monocyclic, or fused-polycyclic ring system (not being a phenyl ring or alkylenedioxyphenyl ring system), whether or not the substance is further modified in any of the following ways:

- (i) by substitution in the ring system to any extent with alkyl, alkenyl, alkynyl, alkoxy, alkylthio, haloalkyl or halo substituents, whether or not further substituted in the ring system by one or more other univalent substituents;
- (ii) by substitution at the 3-position with an alkyl substituent;
- (iii) by substitution at the 2-amino nitrogen atom with one or more alkyl or dialkyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure.

(d) Any substance structurally derived from 3-(1-benzoyl)indole or 3-(1-naphthoyl)indole by modification in any of the following ways:

- (i) by substitution at the nitrogen atom of the indole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl;
- (ii) by replacement of one or more hydrogen atoms of any of the substituents referred to in clause (i), with a halo substituent;

whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl or naphthyl ring to any extent.

(e) 1-Benzylpiperazine or any substance (not being a substance specified in Schedule 3) structurally derived from 1-benzylpiperazine or 1-phenylpiperazine by modification in any of the following ways:

- (i) by substitution at the second nitrogen atom of the piperazine ring with alkyl, benzyl, haloalkyl or phenyl groups;
- (ii) by substitution in the aromatic ring to any extent with alkyl, alkoxy, alkylendioxy, halo or haloalkyl groups.

(f) Any substance (not being a substance specified in Schedule 2) structurally derived from fentanyl by modification in one or more of the following ways, that is to say:

- (i) by replacement of the phenyl portion of the phenethyl group by any heteromonocycle whether or not further substituted in the heterocycle;
- (ii) by substitution in the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo, haloalkyl, amino or nitro groups;
- (iii) by substitution in the piperidine ring with alkyl or alkenyl groups;
- (iv) by substitution in the aniline ring with alkyl, alkoxy, alkylendioxy, halo or haloalkyl groups;
- (v) by substitution at the 4-position of the piperidine ring with any alkoxy-carbonyl or alkoxyalkyl or acyloxy group;

- (vi) by replacement of the *N*-propionyl group by another acyl group.
- (g) Any substance structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the cyclohexyl ring to any extent.
- (h) Any substance structurally derived from 3-(1-naphthoyl)indole or 1*H*-indol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent.
- (i) Any substance structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent.
- (j) Any substance structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent.
- (k) Any substance (not being a substance specified in Schedule 2) structurally derived from pethidine by modification in one or more of the following ways, that is to say:
- (i) by replacement of the 1-methyl group by an acyl, alkyl (whether or not unsaturated), benzyl or phenethyl group, whether or not further substituted;
 - (ii) by substitution in the piperidine ring with alkyl or alkenyl groups or with a propano bridge, whether or not further substituted;
 - (iii) by substitution in the 4-phenyl ring with alkyl, alkoxy, aryloxy, halo or haloalkyl groups;
 - (iv) by replacement of the 4-ethoxycarbonyl by any other alkoxy-carbonyl or any alkoxyalkyl or acyloxy group;
 - (v) by formation of an *N*-oxide or of a quaternary base.
- (l) Any substance (not being methoxyphenamine) structurally derived from phenethylamine, an *N*-alkyl-phenethylamine, α -methylphenethylamine, an *N*-alkyl- α -methylphenethylamine, α -ethylphenethylamine, or an *N*-alkyl- α -ethylphenethylamine by substitution in the ring to any extent with alkyl, alkoxy, alkylenedioxy or halo substituents, whether or not further substituted in the ring by one or more other univalent substituents.

- (m) Any substance structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent.
 - (n) Any fungus containing any proportion of Psilocin or of an ester of Psilocin.
 - (o) 1,2,3,4-Tetrahydronaphthalen-2-amine, 1,2-dihydronaphthalen-2-amine or 2,3-dihydro-1*H*-inden-2-amine or any substance structurally derived from 1,2,3,4-tetrahydronaphthalen-2-amine, 1,2-dihydronaphthalen-2-amine or 2,3-dihydro-1*H*-inden-2-amine by modification in any of the following ways:
 - (i) by substitution in the phenyl ring to any extent with alkyl, alkoxy, alkenyl, alkynyl, alkylthio, alkylendioxy, haloalkyl, hydroxy or halo substituents, whether or not further substituted by one or more other univalent substituents;
 - (ii) by *mono*- or *di*-substitution at the nitrogen atom with alkyl, alkenyl, alkynyl or haloalkyl groups or by inclusion of the nitrogen atom in a cyclic structure.
 - (p) Any substance structurally derived from tryptamine or from a ring-hydroxy tryptamine by substitution at the nitrogen atom of the side-chain with one or more alkyl substituents but no other substituent.
2. Any stereoisomeric form of a substance specified in paragraph 1.
 3. Any ester or ether of a substance specified in paragraph 1 or 2.
 4. Any salt of a substance specified in any of paragraphs 1, 2 or 3.
 5. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 1, 2, 3 or 4, not being a preparation specified in Schedule 5.

SCHEDULE 2

1. The following substances and products, namely:—

Acetorphine

Acetylmethadol

Alfentanil

Allylprodine

Alphacetylmethadol

Alphameprodine

Alphamethadol

Alphaprodine

(3-Amino-2,2-dimethylpropyl)4-aminobenzoate (otherwise known as desethyl dimethocaine)

Anileridine

Benzethidine

Benzylmorphine (3-benzylmorphine)

Betacetylmethadol

Betameprodine

Betamethadol

Betaprodine

Bezitramide

Carfentanil

Clonitazene

Cocaine

Codoxime

4-Cyano-2-dimethylamino-4,4-diphenylbutane

4-Cyano-1-methyl-4-phenylpiperidine

Desomorphine

Dextromoramide

Diamorphine

Diampromide

Diethylthiambutene

Difenoxin

Dihydroetorphine

Dihydromorphine

Dimenoxadole

Dimepheptanol

Dimethocaine

Dimethylthiambutene

Dioxaphetyl butyrate

Diphenoxylate

Dipipanone

Drotebanol

Ecgonine, and any derivative of ecgonine which is convertible to ecgonine or to cocaine

Ethylmethylthiambutene

Etonitazene

Etorphine

Etoxeridine

Fentanyl

Furethidine

Hydrocodone

Hydromorphanol

Hydromorphone

Hydroxypethidine

Isomethadone

Ketobemidone

Levomethorphan

Levomoramide

Levophenacymorphan

Levorphanol

Lofentanil

Medicinal opium

Metazocine

Methadone

(8-Methyl-8-azabicyclo[3.2.1]octan-3-yl)-4-fluorobenzoate (otherwise known as fluorotropacocaine)

Methyldesorphine

Methyldihydromorphine (6-methyldihydromorphine)

2-Methyl-3-morpholino-1,1-diphenylpropane carboxylic acid

1-Methyl-4-phenylpiperidine-4-carboxylic acid

Metopon

Morpheridine

Morphine

Morphine methobromide, morphine *N*-oxide and other pentavalent nitrogen morphine derivatives

Myrophine

Nabilone

Nicomorphine

Noracymethadol

Norlevorphanol

Normethadone

Normorphine

Norpipanone

Oripavine

Oxycodone

Oxymorphone

Pethidine

Phenadoxone

Phenampromide

Phenazocine

Phencyclidine

Phenomorphane

Phenoperidine

1-Phenylcyclohexylamine

4-(1-Phenylcyclohexyl)morpholine

4-Phenylpiperidine-4-carboxylic acid ethyl ester

1-Piperidinocyclohexanecarbonitrile.

Piminodine

Piritramide

Proheptazine

Properidine

Racemethorphan

Racemoramide

Racemorphan

Remifentanyl

Sufentanyl

Tapentadol

Thebacon

Thebaine

4-[1-(2-Thienyl)cyclohexyl]morpholine.

1-[1-(2-Thienyl)cyclohexyl]pyrrolidine

Tilidine

Trimeperidine.

2. Any stereoisomeric form of a substance specified in paragraph 1 not being dextromethorphan or dextrorphan.
3. Any ester or ether of a substance specified in paragraph 1 or 2, not being a substance specified in paragraph 6.
4. Any salt of a substance specified in any of paragraphs 1, 2 or 3.
5. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 1, 2, 3 or 4, not being a preparation specified in Schedule 5.
6. The following substances and products, namely:

Acetyldihydrocodeine

Amineptine

Amphetamine

Amphetaminil

Benzphetamine

Buprenorphine

Butorphanol

Codeine

Dexamphetamine

Dextropropoxyphene

Dihydrocodeine

N-Ethylamphetamine

Ethylmorphine (3-ethylmorphine)

Fenethylamine

Glutethimide

4-Hydroxybutanoic acid

Lefetamine

Lisdexamphetamine

Mecloqualone

Methaqualone

Methylamphetamine

Methylphenidate

Nalbuphine

Nicocodine

Nicodicodine (6-nicotinoyldihydrocodeine)

Norcodeine

Phendimetrazine

Phenmetrazine

Pholcodine

Propiram

Quinalbarbitone

Zipeprol.

7. Any stereoisomeric form of a substance specified in paragraph 6.
8. Any salt of a substance specified in paragraph 6 or 7.
9. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 6, 7 or 8 not being a preparation specified in Schedule 5.

SCHEDULE 3

1. The following substances, namely:—

(a) 2-Benzhydrylpiperidine (otherwise known as desoxypipradrol)

Cathine

1-(3-Chlorophenyl)-4-(3-chloropropyl)piperazine

1-(3-Chlorophenyl)piperazine

Chlorphentermine

Diethylpropion

Ethchlorvynol

Ethinamate

Flunitrazepam

Ketamine

Mazindol

Mephentermine

Meprobamate

Methyprylone

Pemoline

Pentazocine

Phentermine

Pipradrol

Temazepam

(b) any substance (not being quinalbarbitone) structurally derived from barbituric acid by disubstitution at the 5,5 positions, whether or not there is also substitution at the 1-position by a methyl substituent.

2. Any stereoisomeric form of a substance specified in paragraph 1, not being phenylpropanolamine.

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

4. Any preparation or other product containing any proportion of a substance or product specified in paragraphs 1, 2 or 3, not being a preparation specified in Part 2 of Schedule 4 or in Schedule 5.

SCHEDULE 4

PART 1

1. The following substances, namely:—

Alprazolam

Bromazepam

Brotizolam

Camazepam

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepic Acid (clorazepate)

Clotiazepam

Cloxazolam

Delorazepam

Diazepam

Estazolam

Ethyl loflazepate

Fludiazepam

Flurazepam

Halazepam

Haloxazolam

Ketazolam

Loprazolam

Lorazepam

Lormetazepam

Medazepam

Midazolam

Nimetazepam

Nitrazepam

Nordazepam

Oxazepam

Oxazolam

Phenazepam

Pinazepam

Prazepam

Tetraazepam

Triazolam

Zaleplon

Zolpidem

Zopiclone.

2. Any stereoisomeric form of a substance specified in paragraph 1.
3. Any salt of a substance specified in paragraphs 1 or 2.
4. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 1 to 3, not being a preparation specified in Schedule 5.
5. An extract of Cannabis which—
 - (a) is a medicinal product for human use which has been granted a marketing authorisation and which is presented as a liquid formulation for administration to a person through a meter dose pump as a mucosal mouth spray, and
 - (b) has a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per millilitre, where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 to 1.3.
6. Any stereoisomeric form of a substance specified in paragraph 5.
7. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 5 or 6, not being a preparation specified in Schedule 5.

PART 2

1. The following substances namely:-

Aminorex

Fencamfamin

Fenproporex

Mefenorex

Mesocarb

Propylhexedrine

Pyrovalerone

Selegiline

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

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

4. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 1 to 3, not being a preparation specified in Schedule 5.

5. Any preparation containing not more than 100 milligrams of methylphenobarbitone or of phenobarbitone (calculated in either case in terms of base) per dosage unit and no other controlled drug and which in the case of an undivided preparation has a concentration of not more than 0.5 per cent of phenobarbitone (calculated as base) and no other controlled drug.

SCHEDULE 5

1. (a) Any preparation of one or more of the substances to which this paragraph applies (not being a preparation designed for administration by injection) when compounded with one or more other ingredients and which contains a total of not more than 100 milligrams of the substance or substances (calculated as base) per dosage unit and which in the case of an undivided preparation has a total concentration of not more than 2.5 per cent of the substance or substances (calculated as base).

(b) The substances to which this paragraph applies are acetyldihydrocodeine, codeine, ethylmorphine (3-ethylmorphine), nicocodine, nicodicodine (6-nicotinoyldihydrocodeine), norcodeine, pholcodine and their respective salts.
2. Any preparation of dihydrocodeine (not being a preparation designed for administration by injection) containing, per dosage unit, not more than 10 milligrams of dihydrocodeine (calculated as base) and which in the case of an undivided preparation has a concentration of not more than 1.5 per cent of dihydrocodeine (calculated as base).
3. Any preparation of cocaine containing not more than 0.1 per cent of cocaine (calculated as cocaine base), being a preparation which is compounded with one or more other ingredients in such a way that the cocaine cannot be readily recovered.
4. Any preparation of medicinal opium or of morphine (not being a preparation designed for administration by injection) containing, in either case, not more than 0.2 per cent of morphine (calculated as anhydrous morphine base), being a preparation which is compounded with one or more other ingredients in such a way that the opium or morphine cannot be readily recovered.
5. Any preparation of dextropropoxyphene, being a preparation designed for oral administration, containing not more than 135 milligrams of dextropropoxyphene (calculated as base) per dosage unit or with a total concentration of not more than 2.5 per cent, (calculated as base) in undivided preparations.
6. Any preparation of difenoxin containing, per dosage unit, not more than 0.5 milligrams of difenoxin and a quantity of atropine sulphate equivalent to at least 5 per cent of the dose of difenoxin.
7. Any preparation of diphenoxylate containing, per dosage unit, not more than 2.5 milligrams of diphenoxylate (calculated as base), and a quantity of atropine sulphate equivalent to at least 1 per cent of the dose of diphenoxylate.
8. Any preparation of propiram containing, per dosage unit, not more than 100 milligrams of propiram (calculated as base) and which is compounded with at least the same amount, by weight, of methylcellulose.
9. Any powder of ipecacuanha and opium comprising 10 per cent powdered opium, 10 per cent powdered ipecacuanha root, both well mixed with the

remaining 80 per cent consisting of any other powdered ingredient which contains no controlled drug.

10. Any mixture containing one or more of the preparations specified in this Schedule, being a mixture of which none of the other ingredients is a controlled drug.

SCHEDULE 6

Form of Register

Class of Drug

Product

(Insert name, form, strength and pack size as necessary)

Date on which supply received or transaction effected

Name and address of person from whom obtained or to whom supplied

Authority of person supplied to be in possession

Amount

Stock Balance

Obtained

Supplied

SCHEDULE 7

Form of Register

PART 1

Entries to be made in case of obtaining.

Date on which supply received
Name
Address
Amount obtained
Form in which obtained
Of person or firm from whom

PART 2

Entries to be made in case of supply

Date on which the transaction was effected
Name
Address
Particulars as to licence or authority of person or firm supplied to be in possession
Amount supplied
Form in which supplied
Stock Balance
Of person or firm supplied

SCHEDULE 8**DRUGS WHICH PRACTITIONERS WHO ARE REGISTERED NURSES
OR REGISTERED MIDWIVES MAY PRESCRIBE WITHIN
SCHEDULES 2 AND 3****PART 1****Drugs for pain relief in hospital**

Drug	Route of administration
Buprenorphine	Transdermal
Codeine phosphate	Oral
Dihydrocodeine	Oral
Fentanyl	Intranasal, intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal
Morphine sulphate	Intramuscular, intravenous, oral, subcutaneous
Morphine tartrate	Intramuscular, intravenous, subcutaneous
Oxycodone	Oral, subcutaneous, intravenous
Pethidine	Intramuscular, intravenous, subcutaneous

PART 2**Drugs for palliative care**

Drug	Route of administration
Buprenorphine	Transdermal
Codeine phosphate	Oral
Fentanyl	Intranasal, Intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal
Hydromorphone	Oral, subcutaneous
Methylphenidate	Oral
Morphine sulphate	Intramuscular, oral, subcutaneous
Morphine tartrate	Intramuscular, subcutaneous
Oxycodone	Oral, subcutaneous

PART 3**Drugs for purposes of midwifery**

Drug	Route of administration
Pethidine	Intramuscular

PART 4**Drugs for neonatal care**

Drug	Route of administration
Fentanyl	Intravenous, transdermal, transmucosal
Morphine sulphate	Intramuscular, intranasal, intravenous, oral, subcutaneous
Morphine tartrate	Intramuscular, intravenous, subcutaneous

PART 5**Drugs for use in mental health or intellectual disability**

Drug	Route of administration
Methylphenidate	Oral

SCHEDULE 9**Provisions of revoked Regulations of 1988 and corresponding provisions in these Regulations**

Column 1	Column 2	Column 3	Column 4
Old Number	Old Title	New Number	New Title
1	Citation	1	Citation and Commencement
2	Revocations		
3	Interpretation	2	Interpretation
3A	Provisions applicable to practitioners who are registered nurses	3	Provisions applicable to practitioners who are registered nurses or registered midwives
3B	Person may refuse to supply drug if reasonable cause to believe conditions referred to in article 3A have not been satisfied	4	Person may refuse to supply drug if reasonable cause to believe conditions referred to in regulation 3 have not been satisfied
4	General prohibition	5	General prohibition
5	Licences	6	Licences
6	Administration	7	Administration
7	Exemption for practitioners, pharmacists etc.	8	Exemption for practitioners, pharmacists etc.
8	Supply in hospitals etc.	9	Supply
9	General Exemptions	10	General Exemptions
		11	Exemption to possess butan-1,4-diol or dihydrofuran-2(3H)-one
10	Exemption for midwives in respect of pentazocine and pethidine.	12	Exemption for midwives in respect of pentazocine and pethidine.
11	General authorities	13	General authorities
12	Documents to be obtained by a supplier	14	Documents to be obtained by a supplier
13	Form of prescriptions	15	Form of prescriptions
14	Supply on prescriptions	16	Supply on prescription
15	Marking of containers	17	Marking of containers
15A		18	Documents required for export of controlled drugs
16	Keeping of registers for drugs in Schedules 1 and 2	19	Keeping of registers for drugs in Schedules 1 and 2

Column 1	Column 2	Column 3	Column 4
17	Record-keeping in particular cases for drugs in Schedule 2	20	Record-keeping in particular cases for drugs in Schedule 2
18	Keeping of records for drugs in Schedules 3 and 4	21	Keeping of records for drugs in Schedules 3 and 4
19	Preservation of registers, etc.	22	Preservation of registers, etc.
20	Preservation of records for drugs in schedules 3 and 5	23	Preservation of records for drugs in schedules 3, Part 1 of Schedule 4, and Schedule 5
21	Furnishing of information with respect to controlled drugs	24	Furnishing of information with respect to controlled drugs
22	Destruction of certain drugs	25	Destruction of certain drugs
23	Disposal of certain drugs on cessation of business	26	Disposal of certain drugs on cessation of business
24	Forged, etc. prescriptions	27	Forged, etc. prescriptions
25	Publication, sale, etc. of certain books, periodicals and other publications	28	Publication, sale etc. of certain books, periodicals and other publications
26	Amendment of the Misuse of Drugs (safe Custody) Regulations 1982 (S.I. No. 321 of 1982)		
		29	References to revoked Regulations of 1988 in other enactments
27	Transitional provisions	30	Transitional provisions

GIVEN under my Hand,
4 May 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 apply controls to the groups of drugs specified in Schedules 1 to 5 of the Regulations (being drugs to which the Misuse of Drugs Acts 1977 to 2016 apply). The effect of the Regulations is to impose restrictions on the production, supply, importation and exportation of the drugs in question, which vary according to the extent to which these drugs are used for medical or scientific purposes and having regard to the likelihood of their being abused. Appropriate exemptions are provided to cover legitimate use for professional purposes by doctors, pharmacists, nurses and midwives, veterinary practitioners, prison officers, etc. and in other specified circumstances.

In addition to these controls the Regulations specify the classes of persons who may have controlled drugs in their possession and the circumstances in which such possession would not be in contravention of the Act.

The Regulations contain other miscellaneous provisions such as requirements as to the form of prescriptions for controlled drugs, the keeping of books and records, proper documentation relating to export of controlled drugs, arrangements for destruction or disposal of such drugs, and provisions regarding possession of forged prescriptions.

The Regulations also prescribe certain controlled drugs for the purposes of section 5 of the Misuse of Drugs Act 1984.

The Regulations confer authority on certain inspectors, in the Department of Agriculture, Food and the Marine, to lawfully possess Cannabis (hemp) in the course of their duties while monitoring and sampling for the purpose of the relevant EU scheme involving the grant of aid for the production of hemp fibre.

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