STATUTORY RULES OF NORTHERN IRELAND

2002 No. 1

The Misuse of Drugs Regulations (Northern Ireland) 2002

Citation and commencement

1. These regulations may be cited as the Misuse of Drugs Regulations (Northern Ireland) 2002 and shall come into force on 1st February 2002.

Interpretation

2.—(1) The Interpretation Act (Northern Ireland) 1954(1) shall apply to these regulations as it applies to a measure of the Northern Ireland Assembly.

(2) In these regulations, unless the context otherwise requires—

"the Act" means the Misuse of Drugs Act 1971;

"authorised as a member of a group" means authorised by virtue of being a member of a class as respects which the Department has granted an authority under and for the purposes of regulation 8(3), 9(3) or 10(3) which is in force, and "his group authority", in relation to a person who is a member of such a class, means the authority so granted to that class;

"the Department" means the Department of Health, Social Services and Public Safety;

"document" has the same meaning as in Part I of the Civil Evidence Act (Northern Ireland) 1971(2);

"exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where—

- (a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal;
- (b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and
- (c) no one component part of the product or preparation contains more than one milligram of the controlled drug or one microgram in the case of lysergide or any other N-alkyl derivative of lysergamide;

"health prescription" means a prescription issued by a doctor or a dentist under the National Health Service Act 1977(**3**), the National Health Service (Scotland) Act 1978(**4**), the Health and Personal Social Services (Northern Ireland) Order 1972(**5**) or the National Health Service (Isle of Man) Acts 1948 to 1979 (Acts of Tynwald) or upon a form issued by a local authority for use in connection with the health service of that authority;

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972;

^{(1) 1954} c. 33 (N.I.)

^{(2) 1971} c. 36 (N.I.)

⁽**3**) 1977 c. 49

^{(4) 1978} c. 29 (5) S.L. 1072/126

⁽⁵⁾ S.I. 1972/1265 (N.I. 14)

"installation manager" and "offshore installation" have the same meanings as in the Mineral Workings (Offshore Installations) Act 1971(6);

"master" and "seamen" have the same meanings as in the Merchant Shipping Act 1995(7);

"medicinal product" has the same meaning as in the Medicines Act 1968(8);

"officer of customs and excise" means an officer within the meaning of the Customs and Excise Management Act 1979(9);

"prescription" means a prescription issued by a doctor for the medical treatment of a single individual, by a dentist for the dental treatment of a single individual or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment;

"register" means a bound book and does not include any form of loose leaf register or card index;

"registered pharmacy" has the same meaning as in the Medicines Act 1968;

"retail dealer" means a person lawfully conducting a retail pharmacy business or a pharmacist engaged in supplying drugs to the public at a health centre within the meaning of the Medicines Act 1968;

"sister or acting sister" includes any male nurse occupying a similar position;

"wholesale dealer" means a person who carries on the business of selling drugs to persons who buy to sell again.

(2) In these regulations any reference to a regulation or schedule shall be construed as a reference to a regulation contained in these regulations or, as the case may be, to a schedule to these regulations, and any reference in a regulation or schedule to a paragraph shall be construed as a reference to a paragraph of that regulation or schedule.

Specification of controlled drugs for purposes of regulations

3. Schedules 1 to 5 shall have effect for the purpose of specifying the controlled drugs to which certain provisions of these regulations apply.

Exceptions for drugs in Schedules 4 and 5 and poppy-straw

4.—(1) Section 3(1) of the Act (which prohibits the importation and exportation of controlled drugs) shall not have effect in relation to the drugs specified in Schedule 5.

(2) The application of section 3(1) of the Act, in so far as it creates an offence, and the application of sections 50(1) to (4), 68(2) and (3) or 170 of the Customs and Excise Management Act 1979, in so far as they apply in relation to a prohibition or restriction on importation or exportation having effect by virtue of section 3 of the Act, are hereby excluded in the case of importation or exportation by any person for administration to himself of any drug specified in Part II of Schedule 4 which is contained in a medicinal product.

(3) Section 5(1) of the Act (which prohibits the possession of controlled drugs) shall not have effect in relation to—

(a) any drug specified in Part II of Schedule 4 which is contained in a medicinal product;

(b) the drugs specified in Schedule 5.

(4) Sections 4(1) (which prohibits the production and supply of controlled drugs) and 5(1) of the Act shall not have effect in relation to poppy-straw.

^{(6) 1971} c. 61

^{(7) 1995} c. 21

^{(8) 1968} c. 67 (9) 1979 c. 2

(5) Sections 3(1), 4(1) and 5(1) of the Act shall not have effect in relation to any exempt product.

Licences to produce etc controlled drugs

5. Where any person is authorised by a licence of the Department issued under this regulation and for the time being in force to produce, supply, offer to supply or have in his possession any controlled drug, it shall not by virtue of section 4(1) or 5(1) of the Act be unlawful for that person to produce, supply, offer to supply or have in his possession that drug in accordance with the terms of the licence and in compliance with any conditions attached to the licence.

General authority to supply and possess

6.—(1) Notwithstanding the provisions of section 4(1)(b) of the Act, any person who is lawfully in possession of a controlled drug may supply that drug to the person from whom he obtained it.

(2) Notwithstanding the provisions of section 4(1)(b) of the Act, any person who has in his possession a drug specified in Schedule 2, 3, 4 or 5 which has been supplied by or on the prescription of a practitioner for the treatment of that person, or of a person whom he represents, may supply that drug to any doctor, dentist or pharmacist for the purpose of destruction.

(3) Notwithstanding the provisions of section 4(1)(b) of the Act, any 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 veterinary practitioner or veterinary surgeon for the treatment of animals may supply that drug to any veterinary practitioner, veterinary surgeon or pharmacist for the purpose of destruction.

(4) It shall not by virtue of section 4(1)(b) or 5(1) of the Act be unlawful for any person in respect of whom a licence has been granted and is in force under section 16(1) of the Wildlife (Northern Ireland) Order 1985(10) to supply, offer to supply or have in his possession any drug specified in Schedule 2 or 3 for the purposes for which that licence was granted.

(5) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the persons specified in paragraph (7) may supply any controlled drug to any person who may lawfully have that drug in his possession.

(6) Notwithstanding the provisions of section 5(1) of the Act, any of the persons so specified may have any controlled drug in his possession.

- (7) The persons referred to in paragraphs (5) and (6) are—
 - (a) a constable when acting in the course of his duty as such;
 - (b) a person engaged in the business of a carrier when acting in the course of that business;
 - (c) a person engaged in the business of the Post Office when acting in the course of that business;
 - (d) an officer of customs and excise when acting in the course of his duty as such;
 - (e) a person engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of his duty as a person so engaged;
 - (f) a person engaged in conveying the drug to a person who may lawfully have that drug in his possession.

Administration of drugs in Schedules 2, 3, 4 and 5

- 7.—(1) Any person may administer to another any drug specified in Schedule 5.
- (2) A doctor or dentist may administer to a patient any drug specified in Schedule 2, 3 or 4.

(3) Any person other than a doctor or dentist may administer to a patient, in accordance with the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4.

Production and supply of drugs in Schedules 2 and 5

8.—(1) Notwithstanding the provisions of section 4(1)(a) of the Act—

- (a) a practitioner or pharmacist, acting in his capacity as such, may manufacture or compound any drug specified in Schedule 2 or 5;
- (b) a person lawfully conducting a retail pharmacy business and acting in his capacity as such may, at the registered pharmacy at which he carries on that business, manufacture or compound any drug specified in Schedule 2 or 5.

(2) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the following persons, that is to say—

- (a) a practitioner;
- (b) a pharmacist;
- (c) a person lawfully conducting a retail pharmacy business;
- (d) the person in charge or acting person in charge 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;
- (e) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at the hospital or nursing home, the sister or acting sister for the time being in charge of a ward, theatre or other department in such a hospital or nursing home as aforesaid;
- (f) a person who is in charge of a laboratory the recognised activities of which consist in, or include, the conduct of scientific education or research and which is attached to a university, university college or such a hospital as aforesaid or to any other institution approved for the purpose under this sub-paragraph by the Department;
- (g) a public analyst appointed under section 27 of the Food Safety (Northern Ireland) Order 1991(11);
- (h) a sampling officer within the meaning of Schedule 3 to the Medicines Act 1968;
 - (i) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the Health and Personal Social Services (Northern Ireland) Order 1972 and the regulations made thereunder;
- (j) a person authorised by the Department for the purposes of section 110 of the Medicines Act 1968,

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 2 or 5 to any person who may lawfully have that drug in his possession, except that nothing in this paragraph authorises—

- (i) the person in charge or acting person in charge of a hospital or nursing home, having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any drug; or
- (ii) a sister or acting sister for the time being in charge of a ward, theatre or other department to supply any drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a doctor or dentist.

(11) S.I. 1991/762 (N.I. 7)

(3) Notwithstanding the provisions of section 4(1)(b) of the Act, a person who is authorised as a member of a group may, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto, supply or offer to supply any drug specified in Schedule 2 or 5 to any person who may lawfully have that drug in his possession.

(4) Notwithstanding the provisions of section 4(1)(b) of the Act, a person who is authorised by a written authority issued by the Department under and for the purposes of this paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, supply or offer to supply any drug specified in Schedule 5 to any person who may lawfully have that drug in his possession.

- (5) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it; or
 - (b) the installation manager of an offshore installation,

may supply or offer to supply any drug specified in Schedule 2 or 5—

- (i) for the purpose of compliance with any of the provisions specified in paragraph (6), to any person on that ship or installation;
- (ii) to any person who may lawfully supply that drug to him;
- (iii) to any constable for the purpose of the destruction of that drug.

(6) The provisions referred to in paragraph (5) are any provision of, or of any instrument which is in force under—

- (a) the Mineral Workings (Offshore Installations) Act 1971;
- (b) the Health and Safety at Work (Northern Ireland) Order 1978(12); or
- (c) the Merchant Shipping Act 1995.

Production and supply of drugs in Schedules 3 and 4

9.—(1) Notwithstanding the provisions of section 4(1)(a) of the Act—

- (a) a practitioner or pharmacist, acting in his capacity as such, may manufacture or compound any drug specified in Schedule 3 or 4;
- (b) a person lawfully conducting a retail pharmacy business and acting in his capacity as such may, at the registered pharmacy at which he carries on that business, manufacture or compound any drug specified in Schedule 3 or 4;
- (c) a person who is authorised by a written authority issued by the Department under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, produce any drug specified in Schedule 3 or 4.

(2) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the following persons, that is to say—

- (a) a practitioner;
- (b) a pharmacist;
- (c) a person lawfully conducting a retail pharmacy business;
- (d) a person in charge of a laboratory the recognised activities of which consist in, or include, the conduct of scientific education or research;

⁽¹²⁾ S.I. 1978/1039 (N.I. 9)

- (e) a public analyst appointed under section 27 of the Food Safety (Northern Ireland) Order 1991;
- (f) a sampling officer within the meaning of Schedule 3 to the Medicines Act 1968;
- (g) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the Health and Personal Social Services (Northern Ireland) Order 1972 and the regulations made thereunder;
- (h) a person authorised by the Department for the purposes of section 110 of the Medicines Act 1968,

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3 or 4 to any person who may lawfully have that drug in his possession.

- (3) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) a person who is authorised as a member of a group, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto;
 - (b) the person in charge or acting person in charge of a hospital or nursing home;
 - (c) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at that hospital or nursing home, the sister or acting sister for the time being in charge of a ward, theatre or other department in a hospital or nursing home,

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3, or any drug specified in Schedule 4 which is contained in a medicinal product, to any person who may lawfully have that drug in his possession, except that nothing in this paragraph authorises—

- (i) the person in charge or acting person in charge of a hospital or nursing home, having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any drug;
- (ii) a sister or acting sister for the time being in charge of a ward, theatre or other department to supply any drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a doctor or dentist.
- (4) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) a person who is authorised by a written authority issued by the Department under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, supply or offer to supply any drug specified in Schedule 3 or 4 to any person who may lawfully have that drug in his possession;
 - (b) a person who is authorised under paragraph (1)(*c*) may supply or offer to supply any drug which he may, by virtue of being so authorised, lawfully produce to any person who may lawfully have that drug in his possession.
- (5) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it;
 - (b) the installation manager of an offshore installation,

may supply or offer to supply any drug specified in Schedule 3, or any drug specified in Schedule 4 which is contained in a medicinal product—

- (i) for the purpose of compliance with any of the provisions specified in regulation 8(6), to any person on that ship or installation; or
- (ii) to any person who may lawfully supply that drug to him.

(6) Notwithstanding the provisions of section 4(1)(b) of the Act, a person in charge of a laboratory may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3

which is required for use as a buffering agent in chemical analysis to any person who may lawfully have that drug in his possession.

Possession of drugs in Schedules 2, 3 and 4

10.—(1) Notwithstanding the provisions of section 5(1) of the Act—

- (a) a person specified in one of sub-paragraphs (*a*) to (*j*) of regulation 8(2) may have in his possession any drug specified in Schedule 2;
- (b) a person specified in one of sub-paragraphs (a) to (h) of regulation 9(2) may have in his possession any drug specified in Schedule 3 or 4;
- (c) a person specified in regulation 9(3)(b) or (c) or (6) may have in his possession any drug specified in Schedule 3,

for the purpose of acting in his capacity as such a person, except that nothing in this paragraph authorises—

- (i) a person specified in sub-paragraph (e) of regulation 8(2);
- (ii) a person specified in sub-paragraph (c) of regulation 9(3); or
- (iii) a person specified in regulation 9(6),

to have in his possession any drug other than such a drug as is mentioned in the paragraph or subparagraph in question specifying him.

(2) Notwithstanding the provisions of section 5(1) of the Act, a person may have in his possession any drug specified in Schedule 2, 3 or Part I of Schedule 4 for administration for medical, dental or veterinary purposes in accordance with the directions of a practitioner, except that this paragraph shall not have effect in the case of a person to whom the drug has been supplied by or on the prescription of a doctor if—

- (a) that person was then being supplied with any controlled drug by or on the prescription of another doctor and failed to disclose that fact to the first mentioned doctor before the supply by him or on his prescription; or
- (b) that or any other person on his behalf made a declaration or statement, which was false in any particular, for the purpose of obtaining the supply or prescription.

(3) Notwithstanding the provisions of section 5(1) of the Act, a person who is authorised as a member of a group may, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto, have any drug specified in Schedule 2, 3 or Part I of Schedule 4 in his possession.

(4) Notwithstanding the provisions of section 5(1) of the Act—

- (a) a person who is authorised by a written authority issued by the Department under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, have in his possession any drug specified in Schedule 3 or 4;
- (b) a person who is authorised under regulation 9(1)(c) may have in his possession any drug which he may, by virtue of being so authorised, lawfully produce;
- (c) a person who is authorised under regulation 9(4)(a) may have in his possession any drug which he may, by virtue of being so authorised, lawfully supply or offer to supply.
- (5) Notwithstanding the provisions of section 5(1) of the Act—
 - (a) any person may have in his possession any drug specified in Schedule 2, 3 or Part I of Schedule 4 for the purpose of compliance with any of the provisions specified in regulation 8(6);

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

(6) The foregoing provisions of this regulation are without prejudice to the provisions of regulation 4(3)(a).

Exemption for midwives

11.—(1) Notwithstanding the provisions of sections 4(1)(b) and 5(1) of the Act, a registered midwife who has, in accordance with the provisions of rules made under section 14(1)(b) of the Act of 1997, notified to the local supervising authority her intention to practise may, subject to the provisions of this regulation—

- (a) so far as necessary to her professional practice, have in her possession;
- (b) so far as necessary as aforesaid, administer; and
- (c) surrender to the appropriate medical officer such stocks in her possession as are no longer required by her of,

any controlled drug which she may, under and in accordance with the provisions of the Medicines Act 1968 and of any instrument which is in force thereunder, lawfully administer.

(2) Nothing in paragraph (1) authorises a midwife to have in her possession any drug which has been obtained otherwise than on a midwife's supply order signed by the appropriate medical officer.

(3) In this regulation—

"the Act of 1997" means the Nurses, Midwives and Health Visitors Act 1997(13);

"appropriate medical officer" means—

- (a) a medical officer authorised by the Chief Administrative Medical Officer of the Health and Social Services Board area in which the drug was, or is to be, obtained; or
- (b) for the purposes of paragraph (2), a person appointed under and in accordance with section 15 of the Act of 1997 by that authority to exercise supervision over registered midwives within their area, who is for the time being authorised as aforesaid;

"midwife's supply order" means an order in writing specifying the name and occupation of the midwife obtaining the drug, the purpose for which it is required and the total quantity to be obtained.

Cultivation under licence of Cannabis plant

12. Where any person is authorised by a licence of the Department issued under this regulation and for the time being in force to cultivate plants of the genus *Cannabis*, it shall not by virtue of section 6 of the Act be unlawful for that person to cultivate any such plant in accordance with the terms of the licence and in compliance with any conditions attached to the licence.

Approval of premises for cannabis smoking for research purposes

13. Section 8 of the Act (which makes it an offence for the occupier of premises to permit certain activities there) shall not have effect in relation to the smoking of cannabis or cannabis resin for the purposes of research on any premises for the time being approved for the purpose under this regulation by the Department.

Documents to be obtained by supplier of controlled drugs

14.—(1) Where a person (hereafter in this paragraph referred to as "the supplier"), not being a practitioner, supplies a controlled drug otherwise than on a prescription, the supplier 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 supplied (hereafter in this paragraph referred to as "the recipient"); and
- (b) is not authorised by any provision of these regulations other than the provisions of regulation 6(6) and (7)(f) to have that drug in his possession,

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

(2) Where a person (hereafter in this paragraph referred to as "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 has obtained a requisition in writing which—
 - (i) is signed by the person to whom the drug is supplied (hereafter in this paragraph referred to as "the recipient");
 - (ii) states the name, address and profession or occupation of the recipient;
 - (iii) specifies the purpose for which the drug supplied is required and the total quantity to be supplied; and
 - (iv) where appropriate, satisfies the requirements of paragraph (5);
- (b) unless he is reasonably satisfied that the signature is that of the person purporting to have signed the requisition and that that person is engaged in the profession or occupation specified in the requisition,

except that where the recipient is a practitioner and he represents that he urgently requires a controlled drug for the purpose of his profession, the supplier may, if he is reasonably satisfied that the recipient so requires the drug and is, by reason of some emergency, unable before delivery to furnish to the supplier a requisition in writing duly signed, deliver the drug to the recipient on an undertaking by the recipient to furnish such a requisition within the twenty-four hours next following.

(3) A person who has given such an undertaking as aforesaid 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 person in charge or acting person in charge of a hospital or nursing home;
 - (c) a person who is in charge of a laboratory;
 - (d) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it;
 - (e) the master of a foreign ship in a port in Northern Ireland;
 - (f) the installation manager of an offshore installation.
- (5) A requisition furnished for the purposes of paragraph (2) shall—
 - (a) where furnished by the person in charge or acting person in charge of a hospital or nursing home, be signed by a doctor or dentist employed or engaged in that hospital or nursing home;
 - (b) where furnished by the master of a foreign ship, contain a statement, signed by an authorised medical officer of the Health and Social Services Board for the area, within

whose jurisdiction the ship is, that the quantity of the drug to be supplied is the quantity necessary for the equipment of the ship.

(6) Where the person responsible for the dispensing and supply of medicines at any hospital or nursing home supplies a controlled drug to the sister or acting sister for the time being in charge of any ward, theatre or other department in that hospital or nursing home (hereafter in this paragraph referred to as "the recipient") he shall—

- (a) obtain a requisition in writing, signed by the recipient, which specifies the total quantity of the drug 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 pharmacy at which the drug was supplied and a copy of the requisition or a note of it shall be retained or kept by the recipient.

(7) Nothing in this regulation shall have effect in relation to—

- (a) the drugs specified in Schedules 4 and 5 or poppy-straw;
- (b) any drug specified in Schedule 3 contained in or comprising a preparation which—
 - (i) is required for use as a buffering agent in chemical analysis;
 - (ii) has present in it both a substance specified in paragraph 1 or 2 of that Schedule and a salt of that substance; and
 - (iii) is premixed in a kit;
- (c) any exempt product.

Form of prescriptions

15.—(1) Subject to the provisions of this regulation, a person shall not issue a prescription containing a controlled drug other than a drug specified in Schedule 4 or 5 or temazepam unless the prescription complies with the following requirements, that is to say, it shall—

- (a) be in ink or otherwise so as to be indelible and be signed by the person issuing it with his usual signature and dated by him;
- (b) insofar as it specifies the information required by sub-paragraphs (e) and (f) below to be specified, be written by the person issuing it in his own handwriting;
- (c) except in the case of a health prescription, specify the address of the person issuing it;
- (d) if issued by a dentist, have the words "for dental treatment only" written on it and, if issued by a veterinary surgeon or a veterinary practitioner, have a declaration written on it that the controlled drug is prescribed for an animal or herd under his care;
- (e) specify the name and address of the person for whose treatment it is issued or, if it is issued by a veterinary surgeon or veterinary practitioner, of the person to whom the controlled drug prescribed is to be delivered;
- (f) specify the dose to be taken and—
 - (i) in the case of a prescription containing a controlled drug which is a preparation, the form and, where appropriate, the strength of the preparation, and 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;
 - (ii) in any other case, the total quantity (in both words and figures) of the controlled drug to be supplied;

- (g) in the case of a prescription for a total quantity intended to be supplied by instalments, contain a direction specifying the amount of the instalments of the total amount which may be supplied and the intervals to be observed when supplying.
- (2) Paragraph (1)(b) shall not have effect in relation to—
 - (a) a prescription issued by a person approved (whether personally or as a member of a class) for the purposes of this paragraph by the Department; or
 - (b) a prescription containing no controlled drug other than—
 - (i) phenobarbitone;
 - (ii) phenobarbitone sodium; or
 - (iii) a preparation containing a drug specified in paragraph (i) or (ii) above.

(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 (1)(e) if the prescription is written on the patient's bed card or case sheet.

Provisions as to supply on prescription

16.—(1) A person shall not supply a controlled drug other than a drug specified in Schedule 4 or 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 person issuing it is an address within the United Kingdom;
- (c) unless he either is acquainted with the signature of the person by whom it purports to be issued and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine;
- (d) before the date specified in the prescription;
- (e) subject to paragraph (3), later than thirteen weeks after the date specified in the prescription.

(2) Subject to paragraph (3), a person supplying on prescription a controlled drug other than a drug specified in Schedule 4 or 5 shall, at the time of the supply, mark on the prescription the date on which the drug is supplied and, unless it is a health prescription, shall retain the prescription on the premises from which the drug was supplied.

(3) In the case of a prescription containing a controlled drug other than a drug specified in Schedule 4 or 5, which contains a direction that specified instalments of the total amount may be supplied at stated intervals, the person supplying the drug shall not do so otherwise than in accordance with that direction and—

- (a) paragraph (1) shall have effect as if for the requirement contained in sub-paragraph (*e*) thereof there were substituted a requirement that the occasion on which the first instalment is supplied shall not be later than thirteen weeks after the date specified in the prescription;
- (b) paragraph (2) shall have effect as if for the words "at the time of the supply" there were substituted the words "on each occasion on which an instalment is supplied".

Exemption for certain prescriptions

17. Nothing in regulations 15 and 16 shall have effect in relation to a prescription issued for the purposes of a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the Health and Personal Social Services (Northern Ireland) Order 1972 and the regulations made thereunder or to any prescriptions issued for the purposes of the Medicines Act 1968 to a sampling officer within the meaning of that Act.

Marking of bottles and other containers

18.—(1) Subject to paragraph (2), no person shall supply a controlled drug otherwise than in a bottle, package or other container which is plainly marked—

- (a) in the case of a controlled drug other than a preparation, with the amount of the drug contained therein;
- (b) in the case of a controlled drug which is a preparation—
 - (i) made up into tablets, capsules or other dosage units, with 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;
 - (ii) not made up as aforesaid, with 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) the drugs specified in Schedules 4 and 5 or poppy-straw;
 - (b) any drug specified in Schedule 3 contained in or comprising a preparation which-
 - (i) is required for use as a buffering agent in chemical analysis;
 - (ii) has present in it both a substance specified in paragraph 1 or 2 of that Schedule and a salt of that substance; and
 - (iii) is premixed in a kit;
 - (c) any exempt product;
 - (d) the supply of a controlled drug by or on the prescription of a practitioner;
 - (e) the supply of a controlled drug for administration in a clinical trial or a medicinal test on animals.

(3) In this regulation, the expressions "clinical trial" and "medicinal test on animals" have the same meanings as in the Medicines Act 1968.

Record-keeping requirements in respect of drugs in Schedules 1 and 2

19.—(1) Subject to paragraph (3) and regulation 21, every person authorised by or under regulation 5 or 8 to supply any drug specified in Schedule 1 or 2 shall comply with the following requirements, that is to say—

- (a) he shall, in accordance with the provisions of this regulation and of regulation 20, keep a register and shall enter therein in chronological sequence in the form specified in Part I or Part II of Schedule 6, as the case may require, particulars of every quantity of a drug specified in Schedule 1 or 2 obtained by him and of every quantity of such a drug supplied (whether by way of administration or otherwise) by him whether to persons within or outside Northern Ireland;
- (b) he shall use a separate register or separate part of the register for entries made in respect of each class of drugs, and 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, so however that any stereoisomeric form of a drug or its salts shall be classed with that drug.

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

(3) The foregoing provisions of this regulation shall not have effect in relation to—

- (a) in the case of a drug supplied to him for the purpose of destruction in pursuance of regulation 6(2) or (3), a practitioner or pharmacist;
- (b) a person licensed under regulation 5 to supply any drug, where the licence so directs; or
- (c) the sister or acting sister for the time being in charge of a ward, theatre or other department in a hospital or nursing home.

Requirements as to registers

20. Any person required to keep a register under regulation 19 shall comply with the following requirements, that is to say—

- (a) the class of 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 regulation 19 in such a register shall be made on the day on which the drug is obtained or, as the case may be, on which the transaction in respect of the supply of the drug by the person required to make the entry takes place or, if that is not reasonably practicable, 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) such a register shall not be used for any purpose other than the purposes of these regulations;
- (f) a separate register shall be kept in respect of each premises at which the person required to keep the register carries on his business or occupation, but subject to that not more than one register shall be kept at one time in respect of each class of drugs in respect of which he is required to keep a separate register, so, however, that a separate register may, with the approval of the Department, be kept in respect of each department of the business carried on by him;
- (g) every such register in which entries are currently being made shall be kept at the premises to which it relates.

Record-keeping requirements in respect of drugs in Schedule 2 in particular cases

21.—(1) Where a drug specified in Schedule 2 is supplied in accordance with regulation 8(5)(a) (i) to any person on a ship, an entry in the official log book required to be kept under the Merchant Shipping Act 1995 or, in the case of a ship which is not required to carry such an official logbook, 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 drug supplied and, in the case of a report, it is delivered as soon as may be to a superintendent at a Marine Office established and maintained under the Merchant Shipping Act 1995.

(2) Where a drug specified in Schedule 2 is supplied in accordance with regulation 8(5)(b)(i) to a person on an offshore installation, an entry in the installation logbook required to be maintained under the Offshore Installations (Logbooks and Registration of Death) Regulations 1972(14) which specifies the drug supplied shall, notwithstanding anything in these regulations, be a sufficient record of the supply.

(3) A midwife authorised by regulation 11(1) to have any drug specified in Schedule 2 in her possession shall—

⁽¹⁴⁾ S.I. 1972/1542

- (a) on each occasion on which she obtains a supply of such a drug, enter in a book kept by 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 such a drug 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.

Record-keeping requirements in respect of drugs in Schedules 3 and 4

22.—(1) Every person who is authorised under regulation 5 or 9(1)(c) to produce any drug specified in Schedule 3 or 4 shall make a record of each quantity of such a drug produced by him.

(2) Every person who is authorised by or under any provision of the Act to import or export any drug specified in Schedule 3 shall make a record of each quantity of such a drug imported or exported by him.

(3) Every person who is authorised under regulation 9(4) to supply any drug specified in Schedule 4 shall make a record of each quantity of such a drug imported or exported by him.

(4) Paragraph (2) shall not have effect in relation to a person licensed under the Act to import or export any drug where the licence so directs.

Preservation of registers, books and other documents

23.—(1) All registers and books kept in pursuance of regulation 19 or 21(3) shall be preserved for a period of two years from the date on which the last entry therein is made.

(2) Every record made in pursuance of regulation 22 shall be preserved for a period of two years from the date on which the record was made.

(3) Every requisition, order or prescription (other than a health prescription) 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 delivery under it was made.

Preservation of records relating to drugs in Schedules 3 and 5

24.—(1) A producer of any drug specified in Schedule 3 or 5 and a wholesale dealer in any such drug shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him.

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

(3) A retail dealer in any drug specified in Schedule 3, a person in charge or acting person in charge of a hospital or nursing home and a person in charge of a laboratory shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him.

(4) A retail dealer in any drug specified in Schedule 5 shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him.

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

(6) Every document kept in pursuance of this regulation (other than a health prescription) shall be preserved for a period of two years from the date on which it is issued, except 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 paragraph as if it were the keeping of the original document.

Exempt products

25. Nothing in regulations 19 to 24 shall have effect in relation to any exempt product.

Furnishing of information with respect to controlled drugs

26.—(1) The persons specified in paragraph (2) shall on demand made by the Department or by any person authorised in writing by the Department in that behalf—

- (a) furnish such particulars as may be requested in respect of the producing, obtaining or supplying by him of any controlled drug or in respect of any stock of such drugs in his possession;
- (b) for the purpose of confirming any such particulars, produce any stock of such drugs in his possession;
- (c) produce any register, book or document required to be kept under these regulations relating to any dealings in controlled drugs which is in his possession.
- (2) The persons referred to in paragraph (1) are—
 - (a) any person authorised by or under these regulations to produce any controlled drug;
 - (b) any person authorised by or under any provision of the Act to import or export any controlled drug;
 - (c) a wholesale dealer;
 - (d) a retail dealer;
 - (e) a practitioner;
 - (f) the person in charge or acting person in charge of a hospital or nursing home;
 - (g) a person who is in charge of a laboratory;
 - (h) a person who is authorised under regulation 9(4)(a) to supply any controlled drug.

(3) Nothing in this regulation shall require the furnishing of personal records which a person has acquired or created in the course of his profession or occupation and which he holds in confidence; and in this paragraph "personal records" means documentary and other records concerning an individual (whether living or dead) who can be identified from them and relating to his physical or mental health.

Destruction of controlled drugs

27.—(1) No person who is required by any provision of, or by any term or condition of a licence having effect under, these regulations to keep records with respect to a drug specified in Schedule 1, 2, 3 or 4 shall destroy such a drug or cause such a 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 Department hereafter in this regulation referred to as an "authorised person").

(2) An authorised person may, for the purposes 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, or by any term or condition of a licence having effect under, these regulations 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 quantity destroyed and shall be signed by the authorised person in whose presence the drug is destroyed.

(4) Where the master or owner of a ship or installation manager of an offshore installation has in his possession a drug specified in Schedule 2 which he no longer requires, he shall not destroy the drug or cause it to be destroyed but shall dispose of it to a constable, or to a person who may lawfully supply that drug to him.

(5) Nothing in paragraph (1) or (3) shall apply to any person who is required to keep records only by virtue of regulation 22(2) or (3) or 24(3).

(6) Nothing in paragraph (1) or (3) shall apply to the destruction of a drug which has been supplied to a practitioner or pharmacist for that purpose in pursuance of regulation 6(2) or (3).

Revocations

28.—(1) The regulations specified in Schedule 7 are hereby revoked.

(2) Notwithstanding paragraph (1), any register, record, book, prescription or other document required to be preserved under regulation 23 or 24 of the Misuse of Drugs (Northern Ireland) Regulations 1986(15) shall be preserved for the same period of time as if these regulations had not been made.

(3) In the case of a prescription issued before the coming into operation of these regulations, regulation 16(1) shall have effect as if—

- (a) in the case of a prescription containing a controlled drug other than a drug to which the provisions of regulation 15 of the Misuse of Drugs (Northern Ireland) Regulations 1986 applied at the time the prescription was issued, sub-paragraphs (*a*) and (*b*) of that paragraph were omitted; and
- (b) in any other case, for the said sub-paragraphs (*a*) and (*b*) there were substituted the words "unless the prescription complies with the provisions of the Misuse of Drugs (Northern Ireland) Regulations 1986 relating to prescriptions".

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 2nd January 2002.

L.S.

Leslie Frew A Senior Officer of the Department of Health, Social Services and Public Safety