

**2015 No. 891**

**DANGEROUS DRUGS, ENGLAND AND WALES**

**DANGEROUS DRUGS, SCOTLAND**

**The Misuse of Drugs (Amendment) (No. 2) (England, Wales  
and Scotland) Regulations 2015**

*Made* - - - - - *20th March 2015*

*Laid before Parliament* *26th March 2015*

*Coming into force in accordance with regulation 1*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971(a).

In accordance with section 31(3) of that Act the Secretary of State has consulted with the Advisory Council on the Misuse of Drugs.

**Citation, commencement, interpretation, and extent**

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 and, subject to paragraphs (2) and (3), come into force on 1st June 2015.

(2) Regulation 11(d) comes into force on 1st July 2015.

(3) Regulations 10(a), 17 and 19 come into force on 30th November 2015.

(4) In these Regulations the “2001 Regulations” means the Misuse of Drugs Regulations 2001(b).

(5) These Regulations extend to England and Wales and Scotland.

**Amendment of the 2001 Regulations**

2. The 2001 Regulations are amended in accordance with regulations 3 to 19 below.

**Amendment of regulation 2**

3. In regulation 2(1) (interpretation)—

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(a) 1971 c. 38. Section 22 has been amended by section 177(1) of, and paragraph 12 of Schedule 4 to, the Customs and Excise Management Act 1979 (c. 2).

(b) S.I. 2001/3998. Relevant amending instruments are S.I. 2003/1432, S.I. 2003/1653, S.I. 2003/2429, S.I. 2004/1771, S.I. 2005/271, S.I. 2005/1653, S.I. 2005/2864, S.I. 2005/3372, S.I. 2006/986, S.I. 2006/1450, S.I. 2006/2178, S.I. 2007/2154, S.I. 2009/3136, S.I. 2010/1144, S.I. 2010/1799, S.I. 2011/448, S.I. 2012/277 which was not published and was revoked by S.I. 2012/385, S.I. 2012/973, S.I. 2012/1311, S.I. 2013/176, and S.I. 2013/625.

- (a) in the definition of “health prescription”, for “a doctor or a dentist” substitute “a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber or a supplementary prescriber”;
- (b) after the definition of “operating department practitioner” insert—
  - ““organisation providing ambulance services” means one of the following health service organisations—
  - (a) an NHS trust or NHS foundation trust established under the National Health Service Act 2006 which has a function of providing ambulance services;
  - (b) an NHS trust established under the National Health Service (Wales) Act 2006(a) which has a function of providing ambulance services;
  - (c) the Scottish Ambulance Board;” and
- (c) after the definition of “prescription” insert—
  - ““prison” has the same meaning as in section 4(9) of the Regulation of Investigatory Powers Act 2000(b);”.

### **Amendment of regulation 6**

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

- (a) in paragraph (2) after “pharmacist independent prescriber,” insert “a physiotherapist independent prescriber, a chiroprapist independent prescriber,”;
- (b) after paragraph (7) insert—
  - “(8) Notwithstanding the provisions of section 4(1)(b) of the Act, a person lawfully conducting a retail pharmacy business may supply or offer to supply medicines containing phenobarbital or phenobarbital sodium provided that the medicine is supplied (or in the case of an offer to supply would be supplied) in accordance with conditions A to E of regulation 224 or 225 of the Human Medicines Regulations 2012(c)”.

### **New regulation 6C**

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

#### **“Authority for Physiotherapist Independent Prescribers and Chiroprapist Independent Prescribers to prescribe**

**6C.—**(1) A registered physiotherapist independent prescriber may prescribe any of the following controlled drugs for the treatment of organic disease or injury provided that the controlled drug is prescribed to be administered by the specified method—

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

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(a) 2006 c. 41  
 (b) 2000 c. 23. Amendments have been made to section 4 but none is relevant.  
 (c) S.I. 2002/1916

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

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

#### **Amendment of regulation 7**

6. After regulation 7(7) insert—

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

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

#### **Amendment of regulation 8**

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

(a) after paragraph (2)(d) insert

“(da) the person in charge or acting person in charge of an organisation providing ambulance services”;

(b) for paragraph (2)(e) substitute—

“(e) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at a hospital, care home or prison, the senior registered nurse, acting senior registered nurse, or registered midwife, for the time being in charge of a ward, theatre or other department in the hospital, care home or prison.”;

(c) in the second paragraph (2)(i) for “a hospital” substitute “a hospital, organisation providing ambulance services”;

(d) in paragraph (2)(ii) for “senior registered nurse or acting senior registered nurse” substitute “senior registered nurse, acting senior registered nurse or registered midwife”;

(e) after paragraph (2)(iii) insert—

“(iv) the person in charge or acting person in charge of an organisation providing ambulance services to supply any drugs other than directly to employees of the organisation for the immediate treatment of sick or injured persons.”;

(f) for paragraph (8)(b) substitute—

“(b) a registered nurse or a person specified in Schedule 8 may, when acting in their capacity as such, supply or offer to supply, under and in accordance with the terms of a patient group direction, any drug specified in Schedule 5 or ketamine to any person who may lawfully have that drug in his possession, except that this

paragraph shall not have effect in the case of ketamine or any preparation of ketamine which is designed for administration by injection and which is to be used for the purpose of treating a person who is addicted to a drug;” and

(g) after paragraph (8)(b) insert—

“(9) For the purposes of paragraph (8)(b) above, a person shall be regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent upon the drug that he has an overpowering desire for the administration of it to be continued.”.

### **Amendment of regulation 9**

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

(a) in paragraph (3)(b) for “a hospital” substitute “a hospital, organisation providing ambulance services”;

(b) for paragraph (3)(c) substitute—

“(c) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at that hospital, care home or prison, the senior registered nurse, acting senior registered nurse or registered midwife, for the time being in charge of a ward, theatre or other department in the hospital, care home or prison.”;

(c) in paragraph (3)(i) for “a hospital” substitute “a hospital, organisation providing ambulance services”;

(d) in paragraph (3)(ii) for “senior registered nurse or acting senior registered nurse” substitute “senior registered nurse, acting senior registered nurse or registered midwife”; and

(e) after paragraph (3)(iii) insert—

“(iv) the person in charge or acting person in charge of an organisation providing ambulance services to supply any drugs other than directly to employees of the organisation for the immediate treatment of sick or injured persons.”.

### **Amendment of regulation 11**

**9.** In regulation 11 (exemption for midwives)—

(a) in paragraph (1)(b) after “administer” insert “or supply”; and

(b) in paragraph (3) in the definition of “midwife’s supply order” for “obtaining the drug,” substitute “obtaining the drug, the name of the person to whom it is to be administered or supplied.”.

### **Amendment of regulation 14**

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

(a) after paragraph (2)(a)(iv) insert—

“(v) is in the form approved by the Secretary of State, the Welsh Ministers or the Scottish Ministers, for the purposes of requisitioning Schedule 2 and 3 controlled drugs;”;

(b) in paragraph (4)(b) for “a hospital” substitute “a hospital, organisation providing ambulance services”;

(c) after paragraph (4)(i) insert—

“(j) a person who holds a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, or a person who is a registered paramedic”;

(d) for paragraph (5)(a) substitute—

- “(a) where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home;”;
- (e) in paragraph (5)(b) for “the medical officer designated under section 14 of the National Health Service (Scotland) Act 1978” substitute “a health board competent person designated under section 3 of the Public Health etc. (Scotland) Act 2008(a) by the health board”;
- (f) in paragraph (5B)(b) for “hospital or care home” substitute “hospital, organisation providing ambulance services, care home or prison”;
- (g) in paragraph (6) for “any hospital or care home supplies a controlled drug to the senior registered nurse or acting senior registered nurse for the time being in charge of any ward, theatre or other department in that hospital or care home”(b) substitute “any hospital, care home or prison supplies a controlled drug to an operating department practitioner, senior registered nurse, acting senior registered nurse, or registered midwife, for the time being in charge of any ward, theatre or department in that hospital, care home or prison”; and
- (h) after paragraph (7)(c) insert—
  - “(d) subject to paragraph (6) any drug which is required—
    - (i) for use in a prison; or
    - (ii) for use in a care home, which as its whole or main purpose provides palliative care for persons resident there who are suffering from a progressive disease in its final stages.”.

#### **Amendment of regulation 15**

##### **11.** In regulation 15 (form of prescriptions)—

- (a) in paragraph (1) omit “or temazepam”;
- (b) in paragraph (1)(a) after “signature” insert “or be prescribed on an electronic prescription form”;
- (c) in paragraph 1(aa) after “private prescribing” insert “unless prescribed on an electronic prescription form”;
- (d) in paragraph (1)(d) after “his care” insert “and specify the Royal College of Veterinary Surgeons registration number of the veterinary surgeon or veterinary practitioner issuing it”;
- (e) omit paragraph (1A);
- (f) in paragraph (3) for “hospital or care home”(c) substitute “hospital, care home or prison”; and
- (g) after paragraph (3) insert —
  - “(4) In this regulation, “electronic prescription form” has the same meaning as in the National Health Service (Pharmaceutical and Local Pharmaceutical) Regulations 2013(d).”.

#### **Amendment of regulation 16**

**12.** In paragraph (1A) of regulation 16 (provisions as to supply on prescription) omit “or temazepam”.

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(a) 2008 asp 5  
 (b) Both references to “care home”, and the reference to “senior registered nurse or acting senior registered nurse”, were inserted by regulation 4(1) and (3)(c), and (4)(c), respectively, of S.I. 2007/2154.  
 (c) The reference to “care home” was inserted by regulation 4(1) and (3)(d) of S.I. 2007/2154.  
 (d) S.I. 2013/349

### **Amendment of regulation 19**

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

“(c) the senior registered nurse, acting senior registered nurse or registered midwife, for the time being in charge of a ward, theatre or other department in a hospital, care home or prison.”.

### **Amendment of regulation 21**

**14.** In regulation 21 (record-keeping requirements in respect of drugs in Schedule 2 in particular cases)—

- (a) in paragraph (3)(a), for “the amount” substitute “the name of the person to whom it is to be administered or supplied, the amount”; and
- (b) in paragraph (3)(b)—
  - (i) after “administering” insert “or supplying”; and
  - (ii) for “the amount” substitute “the name of the person to whom it was administered or supplied, the amount”.

### **Amendment of regulation 24**

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

### **Amendment of regulation 26**

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

### **Amendment of Schedule 2**

**17.** In paragraph 1 of Schedule 2 (which specifies controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27) after “Isomethadone” insert—

“Ketamine”.

### **Amendment of Schedule 3**

**18.** In the heading of Schedule 3 (which specifies controlled drugs subject to the requirements of regulations 14,15 (except Temazepam), 16, 18, 22, 23, 24, 26 and 27) omit “(except Temazepam)”.

### **Amendment of Schedule 4**

**19.** In paragraph 1 of Part 1 of Schedule 4 (which specifies controlled drugs subject to the requirements of regulations 22, 23, 26 and 27) omit “Ketamine”.

### **Transitional provisions**

**20.** Where a supplier obtained a requisition under regulation 14(2) of the 2001 Regulations before 30th November 2015 regulation 10(a) of these Regulations does not apply in respect of that requisition.

**21.** In the case of a prescription issued under regulation 15(1)(d) of the 2001 Regulations before 1st July 2015 regulation 16(1)(a) of the 2001 Regulations has effect as if regulation 15(1)(d) had not been amended by these Regulations.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Misuse of Drugs Regulations 2001 (the “2001 Regulations”) by including within the definition of “health prescription” contained in regulation 2(1) of the 2001 Regulations a nurse independent prescriber, a pharmacist independent prescriber and a supplementary prescriber as persons who may issue such a prescription. They also insert a definition of an “organisation providing ambulance services” and a “prison.”

Regulations 6 and 7 of the 2001 Regulations are amended to give limited prescribing powers for certain controlled drugs to registered physiotherapists and registered chiropractors. Regulation 6 is also amended to allow the emergency supply (or offer to supply) of phenobarbital or phenobarbital sodium by a person lawfully conducting a retail business, subject to certain conditions.

Regulation 8 of the 2001 Regulations is amended by including within paragraph (2), in relation to the supply or offer to supply any drug specified in Schedule 2 or 5 to the 2001 Regulations, a person who is in charge, or is acting person in charge, of an organisation providing ambulance services, and by substituting a new paragraph (2)(e) which includes reference to the supply of such a drug in a prison and to a senior registered midwife or acting senior registered midwife. Regulation 8(b) is also amended to exempt ketamine from the restrictions on supplying or offering to supply controlled drugs, where this is done by specified healthcare professionals in accordance with the terms of a Patient Group Direction, except where the drug is administered for the purposes of treating addiction.

Regulation 9 of the 2001 Regulations is amended by including in paragraph (3), in relation to the supply or offer to supply any drug specified in Schedules 3 and 4 to the 2001 Regulations, a person who is in charge, or is acting person in charge, of an organisation providing ambulance services.

The definition of “midwife’s supply order” contained in regulation 11(3) of the 2001 Regulations is amended by including the name of the person to whom the relevant drug is administered or supplied within such an order, and the record-keeping requirements contained in regulation 21(3) of the 2001 Regulations are amended to require record-keeping by a midwife when the relevant drugs are supplied to a person as well as when administered.

Regulation 14 of the 2001 Regulations is amended by specifying that the form of requisition to be obtained by a supplier of controlled drugs is to be in the form approved by the Secretary of State, the Welsh Ministers or the Scottish Ministers. A person who is in charge, or is acting person in charge, of an organisation providing ambulance services, an operating department practitioner and a person who holds a certificate of proficiency in ambulance paramedic skills are added to the list of recipients in regulation 14(4) of the 2001 Regulations. The requisition required under regulation 14(5)(b) is updated to refer to the Public Health etc. (Scotland) Act 2008 (asp 5) and the requisition required under regulation 14(6) applying when a controlled drug is supplied, in any hospital, care home, to an operating department practitioner, senior registered nurse or acting senior registered nurse, is widened to include a senior registered midwife or acting senior registered midwife and to include prisons. New paragraph (7)(d) is inserted into regulation 14 providing that nothing in that regulation shall have effect in relation to any drug which is required for use in a prison or care home, which as its whole or main purpose provides palliative care, subject to the provisions of paragraph (6).

Regulations 15 and 16 of the 2001 Regulations are amended by removing references to temazepam, so that it is no longer exempt from the requirements relating to the form of prescriptions. Also, in relation to regulation 15, paragraphs 1(1) and 1(aa) are amended to enable

the electronic prescribing of Schedule 2 and 3 drugs. Paragraph 1(d) is amended to require prescriptions issued by a veterinary surgeon or veterinary practitioner to include the registration number of the person issuing it.

Regulation 19(3) of the 2001 Regulations, in respect of those persons to whom the record-keeping requirements set out in that regulation do not have effect, is amended to include a senior registered nurse or acting senior registered nurse, and a senior registered midwife or acting senior registered midwife. Regulation 21 is amended to include record keeping in respect of administration or supply.

Regulations 24 and 26 of the 2001 Regulations, in relation to the preservation of records relating to drugs in Schedules 3 and 5 and the furnishing of information with respect to controlled drugs respectively, are amended to refer to a person who is in charge, or is acting person in charge, of an organisation providing ambulance services.

Ketamine is moved from Part 1 of Schedule 4 to Schedule 2 to the 2001 Regulations. The heading of Schedule 3 is amended to remove the reference to temazepam being exempt from the requirements of regulation 15 of the 2001 Regulations. The schedule of the Regulations in which a controlled drug is placed affects the extent to which the drug can be lawfully imported, exported, produced, supplied or possessed. The controlled drugs placed in Schedule 1 to the Regulations are those subject to the tightest controls.

The requirement to use a mandatory form for the requisitioning of Schedules 2 and 3 controlled drugs shall not apply to requisitions issued before the coming into force of these Regulations.

The requirement to include a Royal College of Veterinary Surgeons registration number on a veterinary prescription for Schedules 2 and 3 controlled drugs shall not apply to veterinary prescriptions issued prior to 1st July 2015.

Full impact assessments of the effect that this instrument will have on the costs of business and the voluntary sector are available and published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).

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