STATUTORY INSTRUMENTS

2007 No. 2154

DANGEROUS DRUGS, ENGLAND AND WALES

DANGEROUS DRUGS, SCOTLAND

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

Made - - - - *23rd July 2007*

Laid before Parliament *26th July 2007*

Coming into force in accordance with regulation 2

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

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

Citation, interpretation and extent

1.—(1) These Regulations may be cited as the Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007.

(2) In these Regulations—

(a) "the 1973 Regulations" means the Misuse of Drugs (Safe Custody) Regulations 1973(**b**); and

(b) "the 2001 Regulations" means the Misuse of Drugs Regulations 2001(**c**).

(3) These Regulations extend to England, Wales and Scotland.

Commencement

2.—(1) Subject to paragraphs (2), (3) and (4), these Regulations shall come into force on 16th August 2007.

(2) Regulation 4(11)(b) shall come into force on 1st September 2007.

(3) The following regulations shall come into force on 1st January 2008—

(a) regulation 3(4);

(**a**) 1971 c.38.
(**b**) S.I. 1973/798, amended by S.I. 2001/1149.
(**c**) S.I. 2001/3998, to which there are a number of amendments, the relevant ones being made by S.I. 2003/1432, S.I. 2003/2429, S.I. 2005/271, S.I. 2005/2864, S.I. 2005/3372, S.I. 2006/986, S.I. 2006/1450 and S.I. 2006/2178.

(b) regulation 4(6)(e);

(c) regulation 4(8);

(d) regulation 4(11)(a);

(e) regulation 4(13) to (14).

(4) The following regulations shall come into force on 1st February 2008—

(a) regulation 4(9) to (10);

(b) regulation 4(15).

Amendments to the Misuse of Drugs (Safe Custody) Regulations 1973

3.—(1) The 1973 Regulations shall be amended as follows.

(2) In regulation 2—

(a) after the definition of "the Act" insert—

""care home" in relation to—

(a) England and Wales has the same meaning as in the Care Standards Act 2000(**a**); and

(b) Scotland means the accommodation provided by a care home service;

"care home service" has the same meaning as in the Regulation of Care (Scotland) Act 2001(**b**);";

(b) omit paragraphs (2) and (3).

(3) For regulation 3(1), substitute—

"This regulation applies to the following premises—

(a) those occupied by a retail dealer for the purposes of his business;

(b) a care home.".

(4) In paragraph 3 of Schedule 1, after "Methyprylone" insert "(ha) Midazolam".

Amendments to the Misuse of Drugs Regulations 2001

4.—(1) The 2001 Regulations shall be amended as follows.

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

(a) after the definition of "the Act", insert—

""accountable officer" has the same meaning as in the Health Act 2006(**c**);";

(b) after the definition of "authorised as a member of a group", insert—

""care home" in relation to—

(a) England and Wales has the same meaning as in the Care Standards Act 2000; and

(b) Scotland means the accommodation provided by a care home service;

"care home service" has the same meaning as in the Regulation of Care (Scotland) Act 2001;";

(c) after the definition of "officer of customs and excise", insert—

""operating department practitioner" means a person who is registered under the Health Professions Order 2001(**d**) as an operating department practitioner;";

(d) after the definition of "register" insert—

(**a**) 2000 c.14.
(**b**) 2001 asp 8.
(**c**) 2006 c.28.
(**d**) S.I. 2001/254 as amended by S.I. 2004/2033.

""registered chiropodist" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**a**);";

(e) for the definition of "registered ophthalmic optician", substitute—

""registered optometrist" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**b**);

"registered orthoptist" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**c**);";

(f) after the definition of "registered orthotist and prosthetist" insert—

""registered paramedic" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**d**);";

(g) after the definition of "registered pharmacy" insert—

"registered physiotherapist" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**e**);

"registered radiographer" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**f**);";

(h) omit the definitions of "sister or acting sister", "state registered chiropodist" and "state registered paramedic".

(3) For "nursing home", in each place those words appear in the following regulations, substitute "care home"—

(a) regulation 8(2)(**g**) (production and supply of drugs in Schedules 2 and 5);

(b) regulation 9(3) (production and supply of drugs in Schedules 3 and 4);

(c) regulation 14(4)(**h**), 14(5) and 14(6) (documents to be obtained by supplier of controlled drugs);

(d) regulation 15(3) (form of prescriptions);

(e) regulation 19(3) (record-keeping requirements in respect of drugs in Schedules 1 and 2);

(f) regulation 24(3) (preservation of records relating to drugs in Schedules 3 and 5); and

(g) regulation 26(2)(**i**) (furnishing of information with respect to controlled drugs).

(4) For "sister or acting sister", in each place those words appear in the following regulations, substitute "senior registered nurse or acting senior registered nurse"—

(a) regulation 8(2) (production and supply of drugs in Schedules 2 and 5);

(b) regulation 9(3) (production and supply of drugs in Schedules 3 and 4);

(c) regulation 14(6) (documents to be obtained by supplier of controlled drugs);

(d) regulation 19(3) (record-keeping requirements).

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

(a) after paragraph (2)(e), insert—

"(ea) in the case of such a drug supplied to him by a person responsible for the dispensing and supply of medicines at a hospital, an operating department practitioner practising in that hospital;";

(b) at the end of paragraph (2)(i), omit "or";

(**a**) S.I. 1997/1830. The definition of "registered chiropodist" was inserted by S.I. 2003/1590.
(**b**) S.I. 1997/1830. The definition of "registered optometrist" was inserted by S.I. 2005/848.
(**c**) S.I. 1997/1830. The definition of "registered orthoptist" was inserted by S.I. 2003/1590.
(**d**) S.I. 1997/1830. The definition of "registered paramedic" was inserted by S.I. 2003/1590.
(**e**) S.I. 1997/1830. The definition of "registered physiotherapist" was inserted by S.I. 2003/1590.
(**f**) S.I. 1997/1830. The definition of "registered radiographer" was inserted by S.I. 2003/1590.
(**g**) Regulation 8(2) was amended by S.I. 2005/271.
(**h**) Regulation 14(4)(g) was inserted by S.I. 2005/271.
(**i**) Regulation 26(2)(i) was inserted by S.I 2005/271.

(c) in paragraph (2)(ii) for "doctor or dentist." substitute "doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (2A), a nurse independent prescriber; or";

(d) after paragraph (2)(ii), insert—

"(iii) an operating department practitioner to supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (2A), a nurse independent prescriber.";

(e) after paragraph (2), insert—

"(2A) The directions given by a nurse independent prescriber referred to in paragraph (2)(ii) and (iii) shall relate only to a controlled drug which she may prescribe under regulation 6B and a purpose for which it may be prescribed under that regulation.".

(6) In regulation 9 (production and supply of drugs in Schedules 3 and 4)—

(a) after paragraph (3)(c), insert—

"(d) in the case of such a drug supplied to him by a person responsible for the dispensing and supply of medicines at a hospital, an operating department practitioner practising in that hospital;";

(b) in paragraph (3)(ii) for "doctor or dentist." substitute "doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (3A), a nurse independent prescriber; or";

(c) after paragraph (3)(ii), insert—

"(iii) an operating department practitioner to supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (3A), a nurse independent prescriber.";

(d) after paragraph (3), insert—

"(3A) The directions given by a nurse independent prescriber referred to in paragraph (3)(ii) and (iii) shall relate only to a controlled drug which she may prescribe under regulation 6B and a purpose for which it may be prescribed under that regulation.";

(e) in paragraph (8), after "any drug specified in Schedule 4" insert "or Midazolam".

(7) In regulation 10 (possession of drugs in Schedules 2, 3 and 4)—

(a) in paragraphs (1)(c) and (d), for "regulation 9(3)(b) or (c)" substitute "regulation 9(3)(b) to (d)";

(b) in paragraph (1)(i), after "sub-paragraph (e)" insert "or (ea)";

(c) in paragraph (1)(ii), after "sub-paragraph (c)" insert "or (d)".

(8) In regulation 14 (documents to be obtained by supplier of controlled drugs)—

(a) in paragraph (2), for "paragraph" where this first occurs substitute "regulation";

(b) after paragraph (5) insert—

"(5A) Subject to paragraph (5B), on receipt of a requisition (other than a veterinary requisition) mentioned in paragraph (2), the supplier shall—

(a) mark on the requisition in ink or otherwise indelibly his name and address; and

(b) send the requisition to the relevant National Health Service agency in accordance with arrangements specified by that agency.

(5B) Paragraph (5A) shall not apply where the supplier is—

(a) a wholesale dealer; or

(b) a person responsible for the dispensing and supply of medicines at a hospital or care home.";

(c) after paragraph (7) insert—

"(8) In this regulation, "veterinary requisition" means a requisition which states, in accordance with paragraph (2)(ii), that the recipient is a veterinary surgeon or veterinary practitioner.".

(9) In regulation 19 (record-keeping requirements)—

(a) in paragraph (1)(a) for "in the form specified in Part I or II of Schedule 6, as the case may require," substitute "subject to subparagraph (f), using the headings specified in subparagraphs (d) and (e),";

(b) after paragraph (1)(c) insert—

"(d) The headings in respect of entries made for drugs obtained are—

(i) Date supply received;

(ii) Name and address from whom received;

(iii) Quantity received.

(e) The headings in respect of entries made for drugs supplied are—

(i) Date supplied;

(ii) Name/Address of person or firm supplied;

(iii) Details of authority to possess – prescriber or licence holder's details;

(iv) Quantity supplied;

(v) Person collecting Schedule 2 controlled drug (patient/ patient's rep/ healthcare professional) and if healthcare professional, name and address;

(vi) Was proof of identity requested of patient/ patient's rep (Yes/No);

(vii) Was proof of identity of person collecting provided (Yes/No).

(f) The headings at subparagraph (e)(v) to (vii) apply only in respect of drugs specified in Schedule 2.";

(c) for paragraph (2), substitute—

"(2) Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register.";

(d) in paragraph (2A), for "paragraphs (1) and (2)" substitute "paragraph (1)".

(10) In regulation 20 (requirements as to registers), for paragraph (a) substitute "in the separate register or separate part of the register used for each class of drug, a separate page shall be used in respect of each strength and form of that drug and the head of each such page shall specify the class of the drug, its strength and form;".

(11) In regulation 23 (preservation of registers, books and other documents)—

(a) in paragraph (3)—

(i) omit "requisition, order and"; and

(ii) for "regulations" substitute "Regulations";

(b) in paragraph (4) for ", or a copy of such prescription, must" insert "shall".

(12) In regulation 27 (destruction of controlled drugs)—

(a) in paragraph (1), after "the Secretary of State" insert "or, subject to paragraph (1A), an accountable officer";

(b) after paragraph (1), insert—

"(1A) An accountable officer shall not be an authorised person.".

(13) In paragraph 1 of Part 1 of Schedule 4 (controlled drugs subject to the requirements of regulations 22, 23, 26 and 27), omit "Midazolam".

(14) In paragraph 1(a) of Schedule 3 (controlled drugs subject to the requirements of regulations 14 to16, 18, 22 to 24, 26 and 27), after "Methyprylone" insert "Midazolam".

(15) Omit Schedule 6 (form of register).

(16) In paragraph (1) of Schedule 8—

(a) in sub-paragraph (a), after "who is a" omit "state";

(b) for sub-paragraphs (d) to (h) substitute—

"(d) a registered optometrist;

(e) a registered chiropodist;

(f) a registered orthoptist;

(g) a registered physiotherapist;

(h) a registered radiographer;".

Amendments to the Misuse of Drugs (Amendment No. 2) Regulations 2006

5.—(1) The Misuse of Drugs (Amendment No. 2) Regulations 2006(**a**) shall be amended as follows.

(2) In regulation 2 (commencement)—

(a) for "paragraphs (2) and (3)" substitute "paragraph (3)";

(b) omit paragraph (2).

(3) Omit regulations 7(1) and 10.

Amendment to the Misuse of Drugs (Amendment No. 3) Regulations 2006

6. Omit regulation 7 of the Misuse of Drugs (Amendment No. 3) Regulations 2006(**b**) (Amendment to the Misuse of Drugs (Amendment No. 2) Regulations 2006).

Home Office
23rd July 2007

Vernon Coaker
Parliamentary Under Secretary of State

(**a**) S.I. 2006/1450, as amended by S.I. 2006/2178.
(**b**) S.I. 2006/2178.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs (Safe Custody) Regulations 1973 (S.I. 1973/798) ("the 1973 Regulations") and the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) ("the 2001 Regulations"), and make consequential amendments to the Misuse of Drugs (Amendment No. 2) Regulations 2006 (S.I. 2006/1450) and the Misuse of Drugs (Amendment No. 3) Regulations 2006 (S.I. 2006/2178).

Regulation 3(1) to (3) amends the 1973 Regulations to update the references to various premises covered by these Regulations. Regulation 4(2)(b) and (3) update references in the 2001 Regulations to 'nursing home' to 'care home'. Regulation 4(4) updates references in the 2001 Regulations to 'sister' to 'senior registered nurse'. Regulation 4(1)(c) to (h) and 4(16) update definitions of various healthcare practitioners.

Regulation 4(5) to (7) amend regulations 8, 9 and 10 of the 2001 Regulations to allow operating department practitioners to possess and supply or offer to supply any controlled drug specified in Schedules 2, 3 or 5 or any drug specified in Schedule 4 which is contained in a medicinal product, for the purposes of administration to a patient in a ward, theatre or other department, in accordance with the directions of a doctor, dentist, supplementary prescriber acting under a clinical management plan or (to the extent she is authorised to prescribe) a nurse independent prescriber. Regulation 4(5)(c) and 4(6)(b) extend the authority of a senior registered nurse or acting senior registered nurse to supply the same categories of drugs.

Regulation 4(8) amends regulation 14 of the 2001 Regulations so that a person (other than a wholesale dealer or a person responsible for dispensing and supply of medicines at a hospital or care home) who supplies a controlled drug for human use on a requisition must add to that requisition his name and address and send it to the relevant National Health Service agency.

Regulation 4(9) and (15) amend regulation 19 of and omit Schedule 6 to the 2001 Regulations so that the prescribed form of the controlled drugs register is replaced with prescribed headings to be used in that register. Regulation 4(10) amends regulation 20 to impose a requirement that a separate page in the register be used for each strength and form of the drug and that the class of drug, its strength and form be specified at the head of each such page.

Regulation 4(11) amends regulation 23 of the 2001 Regulations so that requisitions no longer need to be preserved for a period of 2 years and that original prescriptions mentioned in regulation 23(4) are to be sent to the relevant National Health Service agency.

Regulation 4(12) amends regulation 27 of the 2001 Regulations to allow accountable officers to authorise people to witness the destruction of controlled drugs.

Regulation 4(13) and (14) reclassify Midazolam from Part I of Schedule 4 to Schedule 3 to the 2001 Regulations. Regulation 4(6)(e) amends regulation 9 of the 2001 Regulations to enable Midazolam to continue to be supplied under a patient group direction and regulation 3(4) amends Schedule 1 to the 1973 Regulations so that Midazolam continues to be an exempted drug under those Regulations.

Regulations 5 and 6 repeal prospective amendments to the 2001 Regulations concerning the format of the controlled drug register which are redundant in consequence of these Regulations.

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