

2006 No.

DANGEROUS DRUGS, ENGLAND AND WALES

DANGEROUS DRUGS, SCOTLAND

The Misuse of Drugs (Amendment No. 2) Regulations 2006

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| <i>Made</i> | - - - - | 2006 |
| <i>Laid before Parliament</i> | | 2006 |
| <i>Coming into force</i> | - - | <i>In accordance with regulation 2</i> |

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, 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 (Amendment No. 2) Regulations 2006.

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

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

Commencement

2.—(1) Subject to paragraphs (2) and (3), these Regulations come into force on 7 July 2006.

(2) Regulations 7(1) and 10 come into force on 1 January 2007.

(3) Regulations 5 and 6(5) in so far as it inserts paragraphs (1C) and (1D) into regulation 16 of the 2001 Regulations come into force in Wales on 1 January 2007.

Amendment of the Misuse of Drugs Regulations 2001

3. The 2001 Regulations shall be amended in accordance with regulations 4 to 11.

4. In regulation 2(1)—

(a) after the definition of “clinical management plan”, insert—

(a) 1971 c.38. Section 22 of that Act was 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, to which there are a number of amendments, the relevant ones being made by S.I. 2003/1653, S.I. 2003/2429, S.I. 2004/1771, S.I. 2005/2864, S.I. 2005/271 and S.I. 2006/986.

- “the Common Services Agency for the health service” means the body established under section 10 of the National Health Service (Scotland) Act 1978(a);”;
- (b) after the definition of “document”, insert—
- ““equivalent body” means a Local Health Board in Wales, a Health Board in Scotland or the Northern Ireland Central Services Agency for the Health and Social Services in Northern Ireland;”;
- (c) after the definition of “exempt product”, insert—
- ““Health Board” means a board constituted under section 2 of the National Health Service (Scotland) Act 1978;”;
- (d) after the definition of “installation manager”, insert—
- ““Local Health Board” means a Local Health Board established in accordance with section 16BA of the National Health Service Act 1977(b);”;
- (e) after the definition of “medicinal product”, insert—
- ““NHS Business Services Authority” means the special health authority established under Article 2 of the NHS Business Services Authority (Awurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(c);
- “the Northern Ireland Central Services Agency for the Health and Social Services” means the body established under Article 26 of the Health and Personal Social Services (Northern Ireland) Order 1972(d);”;
- (f) after the definition of “patient group direction”, insert—
- ““pharmacist” has the same meaning as in the Medicines Act 1968(e);
- “prescriber identification number” means the number recorded against a person’s name by the relevant National Health Service agency for the purposes of that person’s private prescribing;”;
- (g) after the definition of “prescription”, insert—
- ““Primary Care Trust” means a Primary Care Trust established under section 16A of the National Health Service Act 1977(f);
- “private prescribing” means issuing prescriptions other than health prescriptions, where the definition of “prescription” has effect as if the words “or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment” were omitted;
- “professional registration number” means the number recorded against a person’s name in the register of any body that licenses or regulates any profession of which that person is a member;”;
- (h) after the definition of “registered nurse”, insert—
- ““registered occupational therapist” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(g);”;
- (i) after the definition of “registered ophthalmic optician”, insert—
- ““registered orthotist and prosthetist” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(h);”;
- (j) after the definition of “registered pharmacy”, insert—

(a) 1978 c.29. Section 10 of that Act has been amended by paragraph 2(4) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 asp. 13.

(b) 1977 c.49. Section 16BA of that Act was inserted by section 6(1) of the National Health Service Reform and Healthcare Professions Act 2002 (c.17).

(c) S.I. 2005/2414.

(d) S.I. 1972/1265 (NI 14).

(e) 1968 c.67. The definition of “pharmacist” is contained in section 132 of that Act, which was amended by S.I. 1976/1213.

(f) Section 16A of that Act was inserted by section 2(1) of the Health Act 1999 (c.8).

(g) S.I. 1997/1830; the definition of “registered occupational therapist” was inserted by S.I. 2004/1189.

(h) S.I. 1997/1830; the definition of “registered orthotist and prosthetist” was inserted by S.I. 2004/1189.

““relevant National Health Service agency” means, for England and Wales, the NHS Business Services Authority; for Scotland, the Common Services Agency for the health service; and for Northern Ireland, the Northern Ireland Central Services Agency for the Health and Social Services;”.

5.—(1) In regulation 15(1)—

(a) after paragraph (a), insert—

“(aa) except in the case of a health prescription, be written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing;”;

(b) in paragraph (c), after “specify the” insert “prescriber identification number and the”.

(2) After regulation 15(1), insert—

“(1A) A person shall not issue a prescription other than a health prescription containing temazepam unless it is written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing and it specifies the prescriber identification number and the address of the person issuing it.

(1B) Nothing in this regulation prevents the issue of a prescription, other than a health prescription, which is not written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing, containing a controlled drug other than a drug specified in Schedule 4 or 5, where the person issuing the prescription believes on reasonable grounds that the drug will be supplied by a pharmacist in a hospital.”

6.—(1) In regulation 16(1), before “A person” insert “Subject to paragraph (5),”.

(2) In regulation 16(1)(a), before “unless” insert “subject to paragraphs (1A) and (1C),”.

(3) In regulation 16(1)(d), (e), and 16(4)(a) for “date specified in the prescription” substitute “appropriate date”.

(4) In regulations 16(1)(e) and 16(4)(a), for “thirteen weeks” substitute “twenty-eight days”.

(5) After regulation 16(1), insert—

“(1A) A pharmacist may supply a controlled drug other than a drug specified in Schedule 4 or 5 or temazepam if the prescription contains minor typographical errors or spelling mistakes or if it does not comply with the provisions of regulation 15 in the way specified in paragraph (1B), provided that—

- (a) having exercised all due diligence, he is satisfied on reasonable grounds that the prescription is genuine;
- (b) having exercised all due diligence, he is satisfied on reasonable grounds that he is supplying the drug in accordance with the intention of the person issuing the prescription;
- (c) he amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes or so that the prescription complies with the requirements of regulation 15 as the case may be; and
- (d) he marks the prescription so that the amendment he has made under sub-paragraph (c) is attributable to him.

(1B) The way specified in paragraph (1A) is that, in relation to regulation 15(1)(f), the total quantity of the preparation or of the controlled drug or the number of dosage units as the case may be is specified in either words or figures but not both.

(1C) A pharmacist may supply a controlled drug other than a drug specified in Schedule 4 or 5 on a prescription other than a health prescription in a hospital if it does not comply with regulation 15 in the ways specified in paragraph (1D).

(1D) The ways specified in paragraph (1C) are—

- (a) the prescription is not written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing;

- (b) the prescription does not specify the prescriber identification number of the person issuing it.”

(6) After regulation 16(4), insert—

“(5) A person shall not supply a controlled drug specified in Schedule 4 on a prescription later than twenty-eight days after the appropriate date.

(6) A person who is asked to supply on prescription a controlled drug specified in Schedule 2 must first ascertain whether the person collecting the drug is the patient, the patient’s representative or a healthcare professional acting in his professional capacity on behalf of the patient; and—

- (a) where that person is the patient or the patient’s representative, he may—
 - (i) request evidence of that person’s identity; and
 - (ii) refuse to supply the drug if he is not satisfied as to the identity of that person;
- (b) where that person is a healthcare professional acting in his professional capacity on behalf of the patient, he—
 - (i) must obtain that person’s name and address;
 - (ii) must, unless he is acquainted with that person, request evidence of that person’s identity; but
 - (iii) may supply the drug even if he is not satisfied as to the identity of that person.

(7) In this regulation—

“appropriate date” means the later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied;

“healthcare professional” has the same meaning as in the National Health Service Act 1977(a);

“patient” means the person named in the prescription as the person to whom the drug is to be supplied;

“patient’s representative” means a person sent by or on behalf of the patient (other than a healthcare representative acting in his professional capacity).”

7.—(1) After Regulation 19(1)(b), insert—

“(c) in the case of drugs specified in Schedule 2, where the drug was supplied on prescription, he shall in addition enter into the register in the form specified in Part II of Schedule 6, whether the person who collected the drug was the patient, the patient’s representative or a healthcare professional acting on behalf of the patient and —

- (i) if the person who collected the drug was a healthcare professional acting on behalf of the patient, that person’s name and address; or
- (iii) if the person who collected the drug was the patient or the patient’s representative, whether evidence of identity was requested of that person; and whether evidence of identity was provided by the person collecting the drug.”

(2) After regulation 19(2), insert—

“(2A) Subject to regulation 20(e), nothing in paragraphs (1) and (2) shall prevent the use of a register to record additional information to that required or allowed under those provisions.”

8. In regulation 20(e), for “the purposes of”, substitute “purposes related to”.

(a) 1977 c.49. The definition of “healthcare professional” is contained in section 28D(2) of that Act, which was inserted by section 21(1) of the National Health Service (Primary Care) Act 1997 (c.46) and amended by section 177(1), (4) of the Health and Social Care (Community Health and Standards) Act 2003 (c.43).

9. After regulation 23(3), insert—

“(4) Every prescription (other than a health prescription) on which a controlled drug other than a drug specified in Schedule 4 or 5 is supplied, or a copy of such prescription, must be sent to the relevant National Health Service agency in accordance with arrangements specified by that agency.”

10. In Schedule 6, add the following columns to the form under “Part II Entries to be made in case of supply”—

| | | |
|--|--|--|
| Person collecting Schedule 2 controlled drug (patient/patient’s rep/healthcare professional), and if healthcare professional, name and address | Was proof of identity requested of patient/patient’s representative (Yes/No) | Was proof of identity of person collecting provided (Yes/No) |
|--|--|--|

11. In Schedule 8, after paragraph (h), insert—

- “(i) a registered occupational therapist;
- (j) a registered orthotist and prosthetist;”.

Transitional provisions

12. The amendments to the 2001 Regulations made by regulation 6(4) and (6) so far as it relates to the insertion of regulation 16(5) into the 2001 Regulations apply only to prescriptions issued on or after 7 July 2006.

13. In relation to prescriptions issued in Wales before 1 January 2007, regulation 16(1)(a) of the 2001 Regulations shall not apply to persons in England and Scotland in so far as it relates to the requirements for the prescription to be issued on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing and to specify the prescriber identification number of the person issuing it.

Home Office
2006

Parliamentary Under Secretary of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations amend the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) (“the 2001 Regulations”).

Regulation 2 sets out the commencement arrangements for these Regulations.

Regulation 4 inserts a number of new definitions into regulation 2(1) of the 2001 Regulations.

Regulation 5 amends regulation 15 of the 2001 Regulations in respect of private prescriptions issued for human use containing controlled drugs specified in Schedules 1, 2 or 3 to the 2001 Regulations. These prescriptions must be written on a prescription form issued for the purposes of private prescribing by a Primary Care Trust in England, a Local Health Board in Wales or a Health Board in Scotland, and must specify the prescriber identification number of the person issuing it. An exception is, however, created where the issuer of the prescription believes on reasonable grounds that a private prescription is to be supplied by a pharmacist in a hospital: in that case the prescription does not need to be written on a prescription form issued for the

purposes of private prescribing by a Primary Care Trust in England, a Local Health Board in Wales or a Health Board in Scotland. “Prescriber identification number” and “private prescribing” are two of the new defined terms in the 2001 Regulations.

Regulation 6 amends regulation 16 of the 2001 Regulations. It changes the maximum validity period under regulation 16 of the 2001 Regulations for a prescription containing a controlled drug specified in Schedules 1 to 4 to the 2001 Regulations from 13 weeks to 28 days. This will mean that a controlled drug specified in Schedules 1 to 4 to the 2001 Regulations may not be supplied on a prescription (subject to regulation 16(4) of the 2001 Regulations) more than 28 days after the appropriate date as defined in new regulation 16(7) of the 2001 Regulations.

Regulation 6 also amends regulation 16 of the 2001 Regulations to provide exceptions to the requirement under regulation 16(1)(a) of the 2001 Regulations that a person shall not supply a drug specified in Schedules 1, 2 or 3 (except temazepam) to the 2001 Regulations on prescription unless the prescription complies with regulation 15 of the 2001 Regulations.

Regulation 6 also introduces provisions relating to the identification of persons collecting prescriptions for controlled drugs in Schedule 2 to the 2001. Regulations 7 and 10 make consequential changes to the recording requirements and Controlled Drugs Register respectively.

Regulations 8, 9 and 11 make minor amendments to the 2001 Regulations and regulations 12 and 13 contain transitional provisions.