STATUTORY INSTRUMENTS

2012 No. 973

DANGEROUS DRUGS, ENGLAND AND WALES
DANGEROUS DRUGS, SCOTLAND

The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012

Made - - - -	*27th March 2012*
Laid before Parliament	*30th March 2012*
Coming into force - -	*23rd April 2012*

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(**1**).

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 2012 and shall come into force on 23rd April 2012.

(2) In these Regulations the "2001 Regulations" means the Misuse of Drugs Regulations 2001(**2**).

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

Amendment of the 2001 Regulations

2. The 2001 Regulations are amended as follows.

Amendment of regulation 2

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

(a) omit the definition of "medicinal product";

(**1**) 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).

(**2**) 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2007/2154, S.I. 2009/3136, S.I. 2010/1144, S.I. 2010/1799, S.I. 2011/448, and S.I. 2012/277 which was not published and was revoked by S.I. 2012/385.

(b) after the definition of "pharmacist" insert the following definition—

""pharmacist independent prescriber" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(**3**), and such a person may only prescribe controlled drugs in accordance with regulation 6B;"; and

(c) in the definition of "prescription", after "by a nurse independent prescriber for the medical treatment of a single individual,", insert "by a pharmacist independent prescriber for the medical treatment of a single individual,".

Amendment of regulation 4

4. In regulation 4 (exceptions for drugs in Schedules 4 and 5 and poppy-straw)—

(a) in paragraph (2) for "by any person for administration to himself of any drug specified in Part II of Schedule 4 which is contained in a medicinal product" substitute "which is carried out in person for administration to that person of any drug specified in Part II of Schedule 4"; and

(b) in paragraph (3)(a) omit "which is contained in a medicinal product".

Amendment of regulation 6

5. In regulation 6(2) (general authority to supply and possess)—

(a) after "a registered nurse," insert "a pharmacist independent prescriber,"; and

(b) after "a person specified in Schedule 8" insert "acting in accordance with a patient group direction".

Amendment of regulation 6A

6. In regulation 6A(2)(d) (supply of articles for administering or preparing controlled drugs) after "clinical management plan" insert—

"; and

(e) a nurse independent prescriber".

Amendment of regulation 6B

7. For regulation 6B (authority for nurse independent prescribers to prescribe) substitute—

"**6B.** Authority for Nurse Independent Prescribers and Pharmacist Independent Prescribers to prescribe

(1) Subject to paragraph (2) of this regulation, a nurse independent prescriber or a pharmacist independent prescriber may prescribe any controlled drug specified in Schedule 2, 3, 4 or 5.

(2) Neither a nurse independent prescriber nor a pharmacist independent prescriber may prescribe any of the following substances to a person he considers, or has reasonable grounds to suspect, is addicted to any controlled drug listed in the Schedule to the Misuse of Drugs (Supply to Addicts) Regulations 1997(**4**) save for the purpose of treating organic disease or injury:

(a) cocaine, any salt of cocaine, and any preparation or other product containing cocaine or any salt of cocaine;

(**3**) SI 1997/1830, amended by SI 2006/915; there are other amending instruments but none is relevant.
(**4**) SI 1997/1001, amended by SI 2005/2864.

(b) diamorphine, any salt of diamorphine, and any preparation or other product containing diamorphine or any salt of diamorphine;

(c) dipipanone, any salt of dipipanone, and any preparation or other product containing dipipanone or any salt of dipipanone.

(3) For the purposes of paragraph (2) a person is addicted to a controlled drug if, and only if, he has as a result of repeated administration become so dependent upon that controlled drug that he has an overpowering desire for the administration of it to be continued."

Amendment of regulation 7

8. In regulation 7 (administration of drugs in Schedules 2, 3, 4 and 5)—

(a) in paragraph (3) after "any drug specified in Schedule 2, 3 or 4" insert ", and for these purposes the circumstances in which a person is to be regarded as administering in accordance with the directions of a doctor or dentist include where that person is acting in accordance with a patient group direction";

(b) for paragraph (4) substitute—

"(4) Notwithstanding the provisions of paragraph (3), a nurse independent prescriber or a pharmacist independent prescriber may administer to a patient, without the directions of a doctor or dentist, any controlled drug which such nurse independent prescriber or such pharmacist independent prescriber respectively may prescribe under regulation 6B provided it is administered for a purpose for which it may be prescribed under that regulation.";

(c) for paragraph (5) substitute—

"(5) Notwithstanding the provisions of paragraph (3), any person may administer to a patient in accordance with the specific directions of a nurse independent prescriber or a pharmacist independent prescriber any controlled drug which such nurse independent prescriber or such pharmacist independent prescriber respectively may prescribe under regulation 6B provided it is administered for a purpose for which it may be prescribed under that regulation."

Amendment of regulation 8

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

(a) after paragraph (1)(b) insert—

";

(c) a nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2 or 5 for the purposes of administration in accordance with regulation 7;

(d) any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2 or 5 for the purposes of administration in accordance with regulation 7".

(b) in paragraph (2)(k)(ii) after "nurse independent prescriber" insert "or a pharmacist independent prescriber";

(c) in paragraph (2)(k)(iii) after "nurse independent prescriber" insert "or a pharmacist independent prescriber";

(d) for paragraph (2A) substitute—

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

(e) for paragraph (7) substitute—

"(7) Notwithstanding the provisions of section 4(1)(b) of the Act, a nurse independent prescriber may, when acting in her capacity as such, supply or offer to supply any controlled drug specified in Schedule 2 or 5 to any person who may lawfully have any of those drugs in his possession provided it is supplied or offered in circumstances where she may prescribe it under regulation 6B."; and

(f) in paragraph (8)(a)—

(i) after "a registered nurse" insert "or a pharmacist"; and

(ii) for the words "for the treatment of cardiac pain to a person admitted as a patient to a coronary care unit or an accident and emergency department of a hospital" substitute the words "or morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons".

Amendment of regulation 9

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

(a) after paragraph (1)(c) insert—

";

(d) a nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 3 or 4 for the purposes of administration in accordance with regulation 7;

(e) any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 3 or 4 for the purposes of administration in accordance with regulation 7".

(b) in paragraph (3) omit "which is contained in a medicinal product";

(c) in paragraph (3)(ii) after "nurse independent prescriber" insert "or a pharmacist independent prescriber";

(d) in paragraph (3)(iii) after "nurse independent prescriber" insert "or a pharmacist independent prescriber";

(e) for paragraph (3A) substitute—

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

(f) in paragraph (5) omit "which is contained in a medicinal product"; and

(g) for paragraph (7) substitute—

"(7) Notwithstanding the provisions of section 4(1)(b) of the Act, a nurse independent prescriber may, when acting in her capacity as such, supply or offer to supply any controlled drug specified in Schedule 3 or 4 to any person who may lawfully have any of those drugs in his possession provided it is supplied or offered in circumstances where she may prescribe it under regulation 6B."

Amendment of regulation 10

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

(a) in paragraph (1)(d) omit "which is contained in a medicinal product";

(b) for paragraph (1)(e) substitute—

"(e) a person specified in regulation 8(7), regulation 8(8)(a), regulation 9(7) or regulation 9(8) may have in her possession any drug specified in those regulations in accordance with the conditions specified in those regulations,";

(c) in paragraph (2) for "or a nurse independent prescriber, 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, a supplementary prescriber or a nurse independent prescriber" substitute ", a nurse independent prescriber or a pharmacist independent prescriber, 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, a supplementary prescriber, a nurse independent prescriber, a pharmacist independent prescriber or a person specified in Schedule 8 acting in accordance with a patient group direction"; and

(d) in paragraph (2)(a) for "or another nurse independent prescriber and failed to disclose that fact to the first mentioned doctor, supplementary prescriber or nurse independent prescriber" substitute ", another nurse independent prescriber, another pharmacist independent prescriber or another person specified in Schedule 8 acting in accordance with a patient group direction and failed to disclose that fact to the first mentioned doctor, supplementary prescriber, nurse independent prescriber, pharmacist independent prescriber or person specified in Schedule 8 acting in accordance with a patient group direction".

Amendment of regulation 14

12. After regulation 14(4)(g) (documents to be obtained by supplier of controlled drugs) insert—

";

(h) a nurse independent prescriber;

(i) a pharmacist independent prescriber".

Amendment of regulation 18

13. For regulation 18(2)(d) (marking of bottles and other containers) substitute—

"(d) the supply of a controlled drug by or on the prescription of a practitioner, a supplementary prescriber, a nurse independent prescriber or a pharmacist independent prescriber;".

Amendment of regulation 26

14. In regulation 26(2) (furnishing of information with respect to controlled drugs) after "supplementary prescriber" insert—

";

(j) a nurse independent prescriber".

Amendment of Schedule 4

15. For the heading of Part II of Schedule 4 substitute "Controlled Drugs Excepted From the Prohibition on Possession; Excluded from the Application of Offences Arising from the Prohibition on Importation and Exportation when Carried Out in Person for Administration to That Person; and Subject to the Requirements of Regulations 22, 23, 26 and 27".

Amendment of Schedule 8

16. For the reference note at the head of Schedule 8 substitute "Regulations 6(2), 8(8), 9(8) and 10(2)" and in paragraph 1 after "prosthetist" insert—

";

(k) a pharmacist".

Home Office
27th March 2012

Lord Henley
Minister of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations 2001 (the "2001 Regulations") to allow a nurse independent prescriber and a pharmacist independent prescriber (defined in regulation 2(1) of the 2001 Regulations, as amended by regulation 3(b)) to prescribe, possess, supply, offer to supply, administer and give directions for the administration of any controlled drug specified in Schedules 2 to 5 of the 2001 Regulations, but not in relation to cocaine, diamorphine or dipipanone as regards persons addicted to these drugs otherwise than for the purpose of treating organic disease or injury suffered by such persons. The amendments also allow a nurse independent prescriber and a pharmacist independent prescriber to supply certain articles for administering or preparing controlled drugs.

Regulation 8(1)(c) and (d) of the 2001 Regulations (inserted by regulation 9(a)) provides for specified persons to compound any drug specified in Schedule 2 or 5 to the 2001 Regulations for the purposes of administration of that drug in accordance with regulation 7 of the 2001 Regulations, and regulation 9(1)(d) and (e) of the 2001 Regulations (inserted by regulation 10(a)) provides for such compounding in relation to any drug specified in Schedule 3 or 4. Regulation 10(1)(e) of the 2001 Regulations (substituted by regulation 11(b)) allows a person specified in regulations 8(7), 8(8)(a), 9(7) or 9(8) to have in her possession any drug specified in those regulations in accordance with conditions specified in those regulations.

Regulation 12 includes a nurse independent prescriber and a pharmacist independent prescriber within the list of persons in regulation 14(4) of the 2001 Regulations in relation to documentation to be obtained by the supplier of a controlled drug in the circumstances set out in regulation 14. Regulation 13 amends regulation 18 of the 2001 Regulations to the effect that the requirement in regulation 18(1) concerning marking of bottles and other containers does not apply in relation to the supply of a controlled drug by or on the prescription of a nurse independent prescriber or a pharmacist independent prescriber. Regulation 14 amends regulation 26 of the 2001 Regulations to include a nurse independent prescriber within the list of persons in regulation 26(2) in relation to the furnishing of information with respect to controlled drugs.

Regulation 4(a) amends regulation 4(2) of the 2001 Regulations to provide that the application of the provisions referred to in regulation 4(2) are excluded only where a person himself carries out the importation or exportation of the drug specified in Part II of Schedule 4 to the 2001 Regulations. The requirement for such a drug to be contained in a medicinal product is omitted from regulation 4(2) of the 2001 Regulations, as amended by regulation 4(a), and regulations 4(b), 10(a) and (e) and 11(a) make similar amendments. The definition of 'medicinal product' is omitted from regulation 2(1) of the 2001 Regulations, as amended by regulation 3(a).