

2006 No. 915

MEDICINES

**The Medicines for Human Use (Prescribing) (Miscellaneous
Amendments) Order 2006**

<i>Made</i> - - - -	<i>23rd March 2006</i>
<i>Laid before Parliament</i>	<i>3rd April 2006</i>
<i>Coming into force</i> - -	<i>1st May 2006</i>

The Secretary of State for Health and the Department of Health, Social Services and Public Safety, acting jointly, make the following Order in the exercise of powers conferred upon them by sections 57(1) and (2), 58(1), (1A), (4), (4A), (4B) and (5), and 129(4) of the Medicines Act 1968(a), or, as the case may be, the powers conferred by those provisions and now vested in them(b).

In accordance with section 129(6) of that Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by this Order. In accordance with sections 58(6) and 129(7) of that Act, they have consulted and taken into account the advice of the Committee on Safety of Medicines(c).

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 and shall come into force on 1st May 2006.

(2) In this Order—

“the POM Order” means the Prescription Only Medicines (Human Use) Order 1997(d); and

“the Pharmacy and General Sale Order” means the Medicines (Pharmacy and General Sale—Exemption) Order 1980(e).

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- (a) 1968 c.67. The expression “the appropriate Ministers” and the expression “the Health Ministers”, which are relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, and by articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794; section 58 of that Act was amended by section 1 of the Prescription by Nurses etc. Act 1992 (c.28), by section 63 of the Health and Social Care Act 2001 (c.15), by article 54(3) of, and paragraph 2 of Schedule 5 to, S.I. 2002/253, and by regulation 8 of, and paragraph 10 of Schedule 1 to, S.I. 2005/1094.
- (b) In the case of the Secretary of State for Health, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; and in the case of the Department of Health, Social Services and Public Safety, by virtue of the powers vested in the Ministers in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47), which may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c.1); the Department was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1.).
- (c) See paragraph 1 of Part 2 of Schedule 5 to S.I. 2005/2754.
- (d) S.I. 1997/1830; relevant amending instruments are S.I. 1998/108 and 2081, 2002/549, 2003/696, 1590 and 2915, 2004/2, 1189, 1771 and 2693, 2005/765, 1507 and 3324.
- (e) S.I. 1980/1924; relevant amending instruments are S.I. 2000/1919, 2004/1 and 1771, 2005/766 and 2745.

Amendment of article 1 of the POM Order

2. In article 1 of the POM Order (citation, commencement and interpretation), in paragraph (2)—

- (a) after the definition of “Community marketing authorization” insert the following definition—
 - “community practitioner nurse prescriber” means a person—
 - (a) who is a registered nurse or a registered midwife, and
 - (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers’ Formulary for Community Practitioners in the current edition of the British National Formulary;”;
- (b) omit the definition of “district nurse/health visitor prescriber”;
- (c) omit the definition of “Extended Formulary”;
- (d) omit the definition of “extended formulary nurse prescriber”;
- (e) omit the definition of “first level nurse”;
- (f) in the definition of “health prescription”, for “a district nurse/health visitor prescriber or an extended formulary nurse prescriber” substitute “a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber”;
- (g) after the definition of “NHS trust” insert the following definition—
 - “nurse independent prescriber” means a person—
 - (a) who is a registered nurse or a registered midwife, and
 - (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber;”;
- (h) after the definition of “Patient Group Direction” insert the following definition—
 - “pharmacist independent prescriber” means a person—
 - (a) who is a pharmacist, and
 - (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;”;
- (i) in the definition of “registered nurse”, after “Part” insert “or Specialist Community Public Health Nurses’ Part”;
- (j) in the definition of “relevant register”, in paragraph (a), for “first level” substitute “registered”; and
- (k) in the definition of “supplementary prescriber”—
 - (i) in paragraph (a), for “first level” substitute “registered”, and
 - (ii) after “a supplementary prescriber” insert “or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber”.

Amendment of article 2 of the POM Order

3. In article 2 of the POM Order (appropriate practitioners)—

- (a) in paragraph (b), for “district nurse/health visitor prescribers” substitute “community practitioner nurse prescribers”;
- (b) for paragraph (c) substitute the following paragraphs—
 - “(c) in relation to the descriptions and classes of medicinal products specified in article 3A(1), nurse independent prescribers; and

- (d) in relation to the descriptions and classes of medicinal products specified in article 3, other than medicinal products that are controlled drugs, pharmacist independent prescribers.”.

Amendment of article 3A of the POM Order

4. For article 3A of the POM Order (prescribing by extended formulary nurse prescribers)(a) substitute the following article—

“Prescribing and administration by nurse independent prescribers

3A.—(1) Subject to paragraphs (2) and (3), the descriptions and classes of medicinal products in relation to which nurse independent prescribers are appropriate practitioners are—

- (a) prescription only medicines that are not controlled drugs; and
- (b) prescription only medicines that are controlled drugs and which consist of, or contain, one or more of the substances specified in column 1 of Schedule 3A, but which do not contain any other substance or combination of substances which is a controlled drug not included in Schedule 3A.

(2) A nurse independent prescriber may—

- (a) give a prescription for a medicinal product referred to in paragraph (1)(b); or
- (b) if that medicinal product is for parenteral administration—
 - (i) administer that medicinal product, or
 - (ii) give directions for the administration of that medicinal product,

only where he complies with any condition as to the cases or circumstances in which he may do so that is specified in paragraph (3).

(3) If the entry in column 2 of Schedule 3A relating to a substance specifies one or more requirements as to use or route of administration, it is a condition for the purposes of paragraph (2) that a medicinal product which consists of, or contains, that substance is administered, or is prescribed or directed for administration, in accordance with the specified requirements.

(4) A nurse independent prescriber may prescribe or administer a medicinal product referred to in paragraph (1)(b), or give directions for administration of such a product, without complying with any condition specified in paragraph (3) if—

- (a) he is a supplementary prescriber; and
- (b) he complies with the applicable conditions set out in article 3B(3).”

Amendment of article 3B of the POM Order

5. In article 3B of the POM Order (prescribing and administration by supplementary prescribers)(b), in paragraph (2)—

- (a) in sub-paragraph (a), for “district nurse/health visitor prescriber” substitute “community practitioner nurse prescriber”;
- (b) in sub-paragraph (b)—
 - (i) for “an extended formulary nurse prescriber” substitute “a nurse independent prescriber”, and
 - (ii) in head (ii), after “3A(3)” insert “; and”; and
- (c) after sub-paragraph (b), insert the following sub-paragraph—

(a) Article 3A was inserted by S.I. 2002/549 and amended by S.I. 2003/696.

(b) Article 3B was inserted by S.I. 2003/696 and amended by S.I. 2005/765.

- “(c) the supplementary prescriber is a pharmacist independent prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration—
- (i) is a prescription only medicine, and
 - (ii) is not a controlled drug.”.

Amendment of article 3C of the POM Order

6. In article 3C of the POM Order (exemptions from conditions in respect of the cases or circumstances in which an extended formulary nurse prescriber or supplementary prescriber may administer a medicinal product)(a)—

- (a) in the heading, for the words “an extended formulary nurse prescriber” substitute “a nurse independent prescriber”; and
- (b) for “an extended formulary nurse prescriber” substitute “a nurse independent prescriber”.

Amendment of article 8 of the POM Order

7. In article 8 of the POM Order (exemptions for emergency sale or supply)—

- (a) in paragraph (2)—
 - (i) in sub-paragraph (a), for “a district nurse/health visitor prescriber or an extended formulary nurse prescriber” substitute “a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber”,
 - (ii) in sub-paragraph (b), for “district nurse/health visitor prescriber or extended formulary nurse prescriber” substitute “community practitioner nurse prescriber, nurse independent prescriber or pharmacist independent prescriber”, and
 - (iii) in sub-paragraph (c), for “district nurse/health visitor prescriber or extended formulary nurse prescriber” substitute “community practitioner nurse prescriber, nurse independent prescriber or pharmacist independent prescriber”; and
- (b) in paragraph (4), in sub-paragraph (a), in head (ii), for “district nurse/health visitor prescriber or extended formulary nurse prescriber” substitute “community practitioner nurse prescriber, nurse independent prescriber or pharmacist independent prescriber”.

Amendment of article 10 of the POM Order

8. In article 10 of the POM Order (exemption for medicinal products at high dilutions), in paragraph (1), for “or 2” substitute “or in Schedule 2”.

Amendment of article 12 of the POM Order

9. In article 12 of the POM Order (exemption for sale and supply in hospitals), in paragraph (3), for “an extended formulary nurse prescriber” substitute “a nurse independent prescriber”.

Amendment of article 13A of the POM Order

10. In article 13A of the POM Order (exemptions relating to prescriptions given by nurses)(b)—

- (a) in the heading, for “nurses” substitute “certain health professionals”; and
- (b) in paragraph (2)—
 - (i) for “an extended formulary nurse prescriber” substitute “a nurse independent prescriber”, and

(a) Article 3C was inserted by S.I. 2003/696.

(b) Article 13A was inserted by S.I. 2002/549 and amended by S.I. 2003/696 and 2005/765 and 1507.

- (ii) for “the extended formulary nurse prescriber” substitute “the nurse independent prescriber”.

Amendment of article 15 of the POM Order

- 11. In article 15 of the POM Order (prescriptions), in paragraph (2), in sub-paragraph (c)—
 - (a) in head (iii), for “a district nurse/health visitor prescriber, an extended formulary nurse prescriber” substitute “a community practitioner nurse prescriber, a nurse independent prescriber, a pharmacist independent prescriber”; and
 - (b) in head (iv), for “a district nurse/health visitor prescriber, or an extended formulary nurse prescriber” substitute “a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber”.

Substitution of Schedule 2 to the POM Order

- 12. For Schedule 2 to the POM Order(a), substitute the following Schedule—

“SCHEDULE 2

Article 10(1)

SUBSTANCES WHICH MAY BE EXCLUDED FROM THE
CLASS OF PRESCRIPTION ONLY MEDICINES AT HIGH
DILUTION

Codeine and its salts
Dihydrocodeine and its salts
Ethylmorphine and its salts
Morphine and its salts
Medicinal Opium
Pholcodine and its salts”.

Amendment of Schedule 3 to the POM Order

- 13. In Schedule 3 to the POM Order (descriptions and classes of prescription only medicines in relation to which appropriate nurse practitioners are appropriate practitioners), in the heading, for “appropriate nurse practitioners” substitute “community practitioner nurse prescribers”.

Substitution of Schedule 3A to the POM Order

- 14. For Schedule 3A to the POM Order (substances which may be prescribed, administered or directed for administration by extended formulary nurse prescribers and conditions for such prescription or administration)(b), substitute the following Schedule—

“SCHEDULE 3A

Article 3A

CONTROLLED DRUGS WHICH MAY BE PRESCRIBED,
ADMINISTERED OR DIRECTED FOR ADMINISTRATION BY

(a) Schedule 2 was modified by S.I. 2002/549 which revoked article 6.
(b) Schedule 3A was inserted by S.I. 2002/549.

NURSE INDEPENDENT PRESCRIBERS AND CONDITIONS FOR SUCH PRESCRIPTION OR ADMINISTRATION

<i>Column 1</i> <i>Substance</i>	<i>Column 2</i> <i>Requirements as to use or route of administration</i>
Buprenorphine	Transdermal administration in palliative care
Chlordiazepoxide hydrochloride	Oral administration
Codeine Phosphate	Oral administration
Co-Phenotrope	Oral administration
Diamorphine hydrochloride	Oral or parenteral administration
Diazepam	Oral, parenteral or rectal administration
Dihydrocodeine Tartrate	Oral administration
Fentanyl	Transdermal administration in palliative care
Lorazepam	Oral or parenteral administration
Midazolam	Parenteral or buccal administration
Morphine sulphate	Oral, parenteral or rectal administration
Morphine hydrochloride	Rectal administration
Oxycodone hydrochloride	Oral or parenteral administration in palliative care”.

Amendment of the Pharmacy and General Sale Order

- 15.**—(1) The Pharmacy and General Sale Order shall be amended as follows.
- (2) In article 1 (citation, commencement and interpretation), in paragraph (2)—
- (a) omit the definition of “first level nurse”;
 - (b) in the definition of “nurse prescriber”—
 - (i) in paragraph (a), for “first level” substitute “registered”, and
 - (ii) in paragraph (b), after “appliances” insert “as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber”;
 - (c) after the definition of “Patient Group Direction” insert the following definition—

““pharmacist independent prescriber” means a person—

 - (a) who is a pharmacist, and
 - (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;”;
 - (d) after the definition of “registered homeopathic medicinal product for human use” insert the following definitions—

““registered midwife” means a person registered in the Midwives’ Part of the professional register;

“registered nurse” means a person registered in the Nurses’ Part or Specialist Community Public Health Nurses’ Part of the professional register;”;
 - (e) in the definition of “relevant register”, in paragraph (a), for “first level” substitute “registered”; and
 - (f) in the definition of “supplementary prescriber”—
 - (i) in paragraph (a), for “first level” substitute “registered”, and

(ii) after “a supplementary prescriber” insert “or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber”.

(3) In article 4AA (exemption for sale, offer for sale or supply in hospitals and health centres), after “supplementary prescriber” insert “, a pharmacist independent prescriber”.

(4) In Schedule 3, in Part III (classes of individual by whom supplies may be made), omit “Registered health visitors.”.

Signed by authority of the Secretary of State for Health

23rd March 2006

Jane Kennedy
Minister of State,
Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

16th March 2006

Andrew McCormick
Permanent Secretary,
Department of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes further amendments to certain Orders relating to the prescribing, sale and supply of medicines.

Articles 2 to 14 amend the Prescription Only Medicines (Human Use) Order 1997 (“the POM Order”) which specifies the description and classes of medicines (“prescription only medicines”) which may be sold or supplied only in accordance with the prescription of an “appropriate practitioner” and may be administered only by or in accordance with the directions of such a practitioner.

Articles 2 to 6 and 14 amend articles 1, 2 and 3A to 3C of, and Schedule 3A to, the POM Order, so as to make provision for nurses and pharmacists who meet certain conditions, (“nurse independent prescribers” and “pharmacist independent prescribers”) to prescribe and administer prescription only medicines, and remove provisions which applied to “extended formulary nurse prescribers”. In particular, article 3 amends article 2 of the POM Order so that nurse independent prescribers and pharmacist independent prescribers are “appropriate practitioners” able to prescribe prescription only medicines. Article 4 amends Article 3A to define the classes of prescription only medicines which may be prescribed by nurse independent prescribers and specify the conditions as to cases and circumstances in which nurse independent prescribers can prescribe, administer or give directions for administration for certain prescription only medicines containing controlled drugs. Article 14 substitutes a new Schedule 3A which specifies controlled drugs which may be prescribed, administered or directed for administration by nurse independent prescribers and specifies conditions for such use.

Article 2 also makes consequential amendments to article 1 of the POM Order to reflect changes which have been made to the nurses’ professional register and to the entries in that register indicating who is qualified to act as a prescriber.

Articles 2, 3, 5, 7 and 11 also amend the POM Order so as to change the title of certain nurses able to prescribe prescription only medicines specified in Schedule 3 of the POM Order from “district nurse/health visitor prescribers” to “community practitioner nurse prescribers”.

Articles 7, 9 to 11 and 13 of this Order make consequential amendments to the POM Order.

Articles 8 and 12 make amendments consequential on the revocation of article 6 of the POM Order by a previous amending order.

Article 15 amends the Medicines (Pharmacy and General Sale—Exemption) Order 1980 (“the Pharmacy and General Sale Order”) which provides for exemptions from sections 52 and 53 of the Medicines Act 1968 (restrictions on the sale or supply of medicinal products). Article 15 amends articles 1 and 4AA of the Pharmacy and General Sale Order so as to provide an exemption from the restrictions on sale and supply in hospitals and health centres where such sale or supply is in accordance with the written directions of a pharmacist independent prescriber, a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber. Article 15 also makes consequential amendments to article 1 of, and Schedule 3 to, the Pharmacy and General Sale Order to reflect changes which have been made to the nurses’ professional register and to the entries in that register indicating who is qualified to act as a prescriber.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies of the assessment have been placed in the libraries of both Houses of Parliament.

STATUTORY INSTRUMENTS

2006 No. 915

MEDICINES

**The Medicines for Human Use (Prescribing) (Miscellaneous
Amendments) Order 2006**

£3.00

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E0492 3/2006 160492T 19585