

2005 No. 1507

MEDICINES

**The Medicines for Human Use (Prescribing) (Miscellaneous
Amendments) Order 2005**

<i>Made</i> - - - -	<i>6th June 2005</i>
<i>Laid before Parliament</i>	<i>8th June 2005</i>
<i>Coming into force</i> - -	<i>30th June 2005</i>

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Department of Health, Social Services and Public Safety, acting jointly in exercise of the powers conferred upon them by sections 15(1), 57(1) and (2), 58(1), (4), (4A), (4B) and (5) and 129(4) of the Medicines Act 1968(a), or, as the case may be, those powers conferred by the said provisions and now vested in them(b), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order, pursuant to section 129(6) of that Act, and after consulting and taking into account the advice of the Committee on Safety of Medicines, pursuant to sections 58(6) and 129(7) of that Act, and taking into account the advice of the Medicines Commission, pursuant to section 129(7) of that Act, hereby make the following Order:—

PART 1

GENERAL

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 and shall come into force on 30th June 2005.

(2) In this Order—

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

“the Prescribing Order” means the Medicines for Human Use (Prescribing) Order 2005(d);

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- (a) 1968 (c.67). The expression “the appropriate Ministers” and the expression “the 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, by article 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) and by article 54(3) of, and paragraph 2(b) of Schedule 5 to, S.I. 2002/253.
- (b) In the case of the Secretary of State concerned with health in England, 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.I.).
- (c) S.I. 1997/1830; relevant amending instruments are S.I. 2002/549, 2003/ 696, 2004/1771 and 2005/765.
- (d) S.I. 2005/765.

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

PART 2

AMENDMENT OF THE PRESCRIBING ORDER

Amendment of article 1 of the Prescribing Order

2. In article 1 of the Prescribing Order (citation, commencement, extent and interpretation), in paragraph (4)—

- (a) after the definition of “registered midwife”, insert the following definition—

““registered optometrist” means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989(b);”;
- (b) in the definition of “relevant register”—
 - (i) in paragraph (b) omit “and”;
 - (ii) in paragraph (c), after “that register;” insert “and”; and
 - (iii) after paragraph (c), insert—

“(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;
- (c) in the definition of “supplementary prescriber”—
 - (i) in paragraph (c), omit “or”;
 - (ii) in paragraph (d), after “radiographers: diagnostic or therapeutic,” insert “or”; and
 - (iii) after paragraph (d), insert—

“(e) a registered optometrist,”.

PART 3

AMENDMENT OF THE POM ORDER

Amendment of article 1 of the POM Order

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

- (a) after the definition of “the Act”, insert the following definition—

““additional supply optometrist” means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;”;
- (b) in the definition of “relevant register”(c)—
 - (i) in paragraph (b) omit “and”;
 - (ii) in paragraph (c), after “that register” insert “; and”; and
 - (iii) after paragraph (c), insert—

“(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;

(a) S.I. 1980/1924; relevant amending instruments are S.I. 2004/1 and 1771 and 2005/766.

(b) 1989 c.44; section 7 was amended by article 7(1) of the Opticians Act 1989 (Amendment) Order 2005; S.I. 2005/ 848, which will come into force on 30th June 2005.

(c) The definition of relevant register was amended by S.I. 2004/1771 and 2005/765

“6A Persons lawfully conducting a retail pharmacy business within the meaning of section 69.

6A Medicinal products not for parenteral administration, which are prescription only medicines by reason only that they contain any of the following substances:

Acetylcysteine
Atropine sulphate
Azelastine hydrochloride
Diclofenac sodium
Emedastine
Homotropine hydrobromide
Ketotifen
Levocabastine
Lodoxamide
Nedocromil sodium
Olopatadine
Pilocarpine hydrochloride
Polymyxin B/bacitracin
Polymyxin B/trimethoprim
Sodium cromoglycate.

6A The sale or supply shall be subject to the presentation of an order signed by an additional supply optometrist.

6B Additional supply optometrists.

6B Prescription only medicines specified in column 2 of paragraph 6A.

6B The sale or supply shall be only—

- (a) in the course of their professional practice, and
- (b) in an emergency.”.

(2) In the table in Part II of Schedule 5 to the POM Order (Exemptions from the restriction on supply), after paragraph 3, insert the following new paragraph—

“3A Persons employed or engaged in the provision of lawful drug treatment services.

3A Ampoules of sterile water for injection containing not more than 2 mg of sterile water.

3A The supply shall be only in the course of provision of lawful drug treatment services.”.

PART 4

AMENDMENT OF THE PHARMACY AND GENERAL SALE ORDER

Amendment of article 1 of the Pharmacy and General Sale Order

8. In article 1 of the Pharmacy and General Sale Order (citation, commencement and interpretation), in paragraph (2)—

(a) after the definition of “the Act”, insert the following definition—

““additional supply optometrist” means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;”;

(b) for the definition of “registered ophthalmic optician”, substitute—

““registered optometrist” means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;

- (c) in the definition of “relevant register”(a)—
 - (i) in paragraph (b) omit “and”;
 - (ii) in paragraph (c), after “that register” insert “; and”; and
 - (iii) after paragraph (c), insert—
 - “(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;
- (d) in the definition of “supplementary prescriber”(b)—
 - (i) in paragraph (c), omit “or”;
 - (ii) in paragraph (d), after “radiographers: diagnostic or therapeutic,” insert “or”; and
 - (iii) after paragraph (d), insert—
 - “(e) a registered optometrist,”.

Amendment of Schedule 1 to the Pharmacy and General Sale Order

9.—(1) In the table in Part 1 of Schedule 1—

- (a) in paragraph 2, in column 1, for “registered ophthalmic opticians”, substitute “registered optometrists”; and
- (b) after paragraph 2, insert the following new paragraph—

<p>“2A. Additional supply optometrists</p>	<p>2A.Medicinal products which are prescription only medicines by reason only that they contain any of the following substances: Acetylcysteine Atropine sulphate Azelastine hydrochloride Dicofenac sodium Emadastine Homotropine hydrobromide Ketotifen Levocabastine Lodoximide Nedocromil sodium Olopatadine Pilocarpine hydrochloride Polymyxin B/bacitracin Polymyxin B/trimethoprim Sodium Cromoglycate</p>	<p>2A.The sale or supply shall be only in the course of their professional practice and only in an emergency.”.</p>
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(a) The definition of “relevant register” was inserted by S.I. 2004/1 and amended by S.I. 2004/1771 and 2005/766.
 (b) The definition of “supplementary prescriber” was inserted by S.I. 2004/1 and amended by S.I. 2004/1771 and 2005/766.

(2) In the table in Part II of Schedule 1, after paragraph 6, insert the following new paragraph—

“6A. Persons employed or engaged in the provision of lawful drug treatment	6A. Ampoules of sterile water for injection containing not more than 2 mg of sterile water.	6A. The supply shall be only in the course of provision of lawful drug treatment services.”.
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Signed by authority of the Secretary of State for Health

6th June 2005

Jane Kennedy
Minister of State for Quality and Patient Safety,
Department of Health

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



6th June 2005

D. C. Gowdy
Permanent Secretary
Department of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

Part 2 amends the Medicines for Human Use (Prescribing) Order 2005 (“the Prescribing Order”). Article 2 of that Order created a new exemption from the restrictions imposed by sections 7 and 8 of the Medicines Act 1968 (general provisions as to dealing with medicinal products and provisions as to manufacture and wholesale dealing). It provides that the restrictions imposed by those sections shall not apply to the preparation or dispensing or to procuring the preparation or dispensing of a medicinal product for human use in accordance with a prescription given by a supplementary prescriber where this is done by or under the supervision of a pharmacist in a registered pharmacy, hospital or health care centre or, in Scotland, in a care home service.

Article 2 amends the definition of “supplementary prescriber” to include certain registered optometrists, and makes certain other related amendments to the definitions in the Prescribing Order.

Part 3 amends 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 in accordance with the directions of such a practitioner. Article 3 amends article 2 of the POM Order to extend the definition of “supplementary prescriber” to include certain registered optometrists and makes various other related amendments to the definitions in the POM Order. Article 4 makes changes to the list of medicines in article 7 of the POM Order which may be administered parenterally by any person in an emergency.

Article 5 amends article 13A of the POM Order so that a pharmacist may supply a prescription only medicine in accordance with a prescription given by a registered optometrist if, having exercised all due diligence he believes on reasonable grounds that person is a supplementary prescriber. Article 6 amends Schedule 3A to the POM order to make changes to the list of medicines which may be prescribed by extended formulary nurse prescribers.

Article 7 amends Schedule 5 to the POM Order (exemptions from restrictions on supply or administration of prescription only medicines), to provide that, in addition to those medicines which may be sold or supplied in the course of their professional practice by all optometrists, certain other medicines may be sold or supplied by a registered pharmacist to an “additional supply optometrist”, and that those medicines may be sold or supplied by an additional supply optometrist in the course of that person’s professional practice and in an emergency. It also amends Schedule 5 to provide that water for injection may be supplied in the course of a lawful drug treatment service.

Part 4 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 8 amends article 1 of the Pharmacy and General Sale Order to extend the definition of “supplementary prescriber” to include certain optometrists and to make certain other related amendments to the definitions in that Order.

Article 9 amends Schedule 1 to the Pharmacy and General Sale Order to provide that, in addition to those medicines which may be sold or supplied by all registered optometrists, certain additional medicines may be sold or supplied by “additional supply optometrists”. Article 9 also provides that the term “registered ophthalmic optician”, which is used in Schedule 1 is replaced with the term “registered optometrist”. It also amends Schedule 1 to provide that water for injection may be supplied in the course of a lawful drug treatment service.

A Regulatory Impact Assessment in relation to this Order has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10–202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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