
STATUTORY INSTRUMENTS

2005 No. 765

MEDICINES

The Medicines for Human Use (Prescribing) Order 2005

<i>Made</i>	- - - -	<i>16th March 2005</i>
<i>Laid before Parliament</i>		<i>17th March 2005</i>
<i>Coming into force</i>	- -	<i>7th April 2005</i>

As respects England, Scotland and Wales, the Secretary of State in England, and , as respects Northern Ireland, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly in exercise of the powers conferred upon them by sections 15(1), 58(1), (4), (4A), (4B) and (5) and 129(4) of the Medicines Act 1968(1), or, as the case may be, those powers conferred by the said provisions and now vested in them(2), 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:—

Citation, commencement, extent and interpretation

1.—(1) This Order may be cited as the Medicines for Human Use (Prescribing) Order 2005 and shall come into force on 7th April 2005.

(2) Subject to paragraph (3), this Order applies to the whole of the United Kingdom.

(3) Paragraphs (2) and (3) of article 2 extend to Scotland only.

(4) In this Order—

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- (1) 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) and 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.
- (2) 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 and the Department of Agriculture and Rural Development, by virtue of the powers vested in the Ministers in charge of those Departments 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 Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Departments were renamed by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I.I.).

“the Act” means the Medicines Act 1968;

“first level nurse” means a person registered in Sub-Part 1 of the Nurses' Part of the professional register;

“medicinal product” includes any article or substance in respect of which section 58 of the Act has effect by virtue of an order made under section 104 of the Act, but does not include—

- (a) a medicinal product which is a veterinary drug as defined in section 132(1) of the Act; or
- (b) an article or substance in respect of which section 58 has such effect where that article or substance is only to be administered to animals;

“the POM Order” means the Prescription Only Medicines (Human Use) Order 1997(3);

“professional register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(4);

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

“relevant register” means —

- (a) in relation to a first level nurse or registered midwife, the professional register;
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(5) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(6); and
- (c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(7) relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists;
 - (iii) radiographers: diagnostic or therapeutic,that register;

“supplementary prescriber” means—

- (a) a first level nurse;
- (b) a pharmacist;
- (c) a registered midwife; or
- (d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) radiographers: diagnostic or therapeutic,

against whose name is recorded in the relevant register an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber.

(3) S.I. 1997/1830; relevant amending instruments are S.I. 1998/1178, 2000/2899, 2001/2889, 2002/549, 2003/696 and 2915, and 2004/2, 696, 1031, 1189, 1771 and 2693.

(4) S.I. 2002/253.

(5) 1954, c. 61.

(6) S.I. 1976/1213 (N.I. 22)

(7) S.I. 2002/254.

Exemption to the restrictions imposed by sections 7 and 8 of the Medicines Act 1968

2.—(1) The restrictions imposed by sections 7 and 8 of the Medicines Act 1968 do not apply to anything which is done in a registered pharmacy, a hospital or a health centre and is done there by or under the supervision of a pharmacist and consists of—

- (a) preparing or dispensing a medicinal product in accordance with a prescription given by a supplementary prescriber; or
- (b) procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a supplementary prescriber.

(2) The restrictions imposed by sections 7 and 8 of the Medicines Act 1968 do not apply to anything which is done in a care home service and is done there by or under the supervision of a pharmacist and consists of—

- (a) preparing or dispensing a medicinal product in accordance with a prescription given by a supplementary prescriber; or
- (b) procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a supplementary prescriber.

(3) In paragraph (2), “a care home service” has the meaning given by section 2(3) of the Regulation of Care (Scotland) Act 2001⁽⁸⁾.

Amendment of article 1 of the POM Order

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

- (a) in the definition of “relevant register”—
 - (i) in paragraph (a) omit “and”;
 - (ii) in paragraph (b), after “the Pharmacy (Northern Ireland) Order 1976;” insert “and”;
and
 - (iii) after paragraph (b), insert—
 - “(c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) radiographers: diagnostic or therapeutic;
- (b) in the definition of “supplementary prescriber”⁽⁹⁾—
 - (i) in paragraph (b), omit “or”;
 - (ii) in paragraph (c), after “a registered midwife,” insert “or”;
 - (iii) after paragraph (c), insert—
 - “(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or

⁽⁸⁾ 2001 asp8.

⁽⁹⁾ The definition of “supplementary prescriber” was inserted by S.I. 2003/696 and amended by S.I. 2004/1771.

- (iii) radiographers: diagnostic or therapeutic;” and
- (c) after “an annotation”, insert “or entry”.

Amendment of article 3B of the POM Order

4. In article 3B(10) of the POM Order (prescribing and administration by supplementary prescribers), in paragraph (3), omit sub-paragraph (b).

Amendment of article 13A of the POM Order

5. In article 13A(11) of the POM Order (exemptions relating to prescriptions given by nurses), in paragraph (1)—

- (a) in paragraph (b), omit “or”;
- (b) in paragraph (c), after “a registered midwife;”, insert “or”;
- (c) after paragraph (c), insert—
 - “(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) radiographers: diagnostic or therapeutic,”.

Amendment of article 15 of the POM Order

6. For Article 15 of the POM Order (prescriptions)(12), substitute the following article —

“15.—(1) For the purposes of section 58(2)(a), and subject to paragraph (3), a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.

- (2) The conditions referred to in paragraph (1) are that the prescription—
 - (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
 - (b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations(13), in which case it may be written by means of carbon paper or similar material;
 - (c) shall contain the following particulars—
 - (i) the address of the appropriate practitioner giving it,
 - (ii) the appropriate date,
 - (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, a supplementary prescriber, a district nurse/health visitor prescriber,an extended formulary nurse prescriber, a veterinary surgeon or a veterinary practitioner,

(10) Article 3B was inserted by S.I. 2003/696 and amended by S.I. 2004/1031.

(11) Article 13A was inserted by S.I. 2002/549 and amended by S.I. 2003/696.

(12) Relevant amending instruments are S.I. 2001/2889, 2002/549, 2003/696.

(13) S.I. 2001/3998.

- (iv) where the appropriate practitioner giving it is a doctor, dentist, a supplementary prescriber, a district nurse/health visitor prescriber, or an extended formulary nurse prescriber, the name, address and the age, if under 12, of the person for whose treatment it is given, and
 - (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and the address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
 - (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
 - (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.
- (3) For the purposes of paragraph (1) the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (4), unless the prescription is a health prescription for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations or is given by a veterinary surgeon or a veterinary practitioner.
- (4) The conditions referred to in paragraph (3) are that the prescription shall be created in electronic form and signed with an advanced electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries).
- (5) The prohibition on sale or supply imposed by section 58(2)(a) shall not apply where a prescription only medicine is sold or supplied other than in accordance with a prescription given by an appropriate practitioner and –
- (a) the reason the sale or supply is not in accordance with such a prescription is that a condition specified in paragraph (2) or (4) is not fulfilled; and
 - (b) the person selling or supplying the prescription only medicine has exercised all due diligence and believes on reasonable grounds that the condition is fulfilled.
- (6) In paragraph (2) “appropriate date” means—
- (a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and
 - (b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it,
- and, for the purposes of sub-paragraphs (d) and (e) of that paragraph, where the health prescription bears both the date on which it was signed and a date indicated as being that before which it shall not be dispensed, the appropriate date is the later of those dates.
- (7) In this Article—
- “advanced electronic signature” means an electronic signature which is—
- (a) uniquely linked to the signatory,
 - (b) capable of identifying the signatory,
 - (c) created using means that the signatory can maintain under his sole control, and

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(d) which is linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

“electronic communication” means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

(a) by means of a telecommunication system (within the meaning of the Telecommunications Act 1984⁽¹⁴⁾), or

(b) by other means but while in an electronic form; and

“signatory” means the appropriate practitioner giving the prescription.”.

Amendment of Schedule 3A to the POM Order

7. In the table in Schedule 3A to the POM Order⁽¹⁵⁾, (substances which may be prescribed, administered or directed for administration by extended formulary nurse prescribers)—

(a) in column 1 insert, at the appropriate place in the alphabetical order of the entries as they appear in that column, the entry set out in column 1 below, and in column 2, insert, against that entry, the corresponding entry in column 2 below—

<i>Column 1</i>	<i>Column 2</i>
Acetylcysteine	Parenteral
Adrenaline	Parenteral
Alteplase	Parenteral
Amiodarone	Parenteral
Bemiparin sodium	Parenteral
Benzatropine mesilate	Parenteral
Calcipotriol	External
Calcitriol	External
Cefotaxime sodium	Parenteral
Ceftriaxone Sodium	Parenteral
Certoparin sodium	Parenteral
Chlorphenamine maleate	Parenteral
Cimetidine	Parenteral
Cyclizine hydrochloride	Oral
Cyclizine lactate	Parenteral
Dalteparin sodicum	Parenteral
Dexamethasone sodium phosphate	Oral
Dextran 70	Parenteral
Dolesetron mesilate	Oral and parenteral

⁽¹⁴⁾ 1984 (c. 12).

⁽¹⁵⁾ Schedule 3A was inserted by S.I. 2002/549, and amended by S.I. 2003/696 and 2915, and 2004/2, 1189 and 2693.

<i>Column 1</i>	<i>Column 2</i>
Enoxaparin	Parenteral
Furosemide	Oral and parenteral
Gelatin 3.5 – 4%	Parenteral
Glucose 5%	Parenteral
Glucose 5% with Potassium (K ⁺ 40 mmol/L) ready made infusion bag	Parenteral
Granisetron hydrochloride	Parenteral
Heparin sodium	Parenteral for the purpose of cannulae flushing
Hexastarch	Parenteral
Human soluble insulin	Parenteral
Hydroxyethyl starch	Parenteral
Levomepromazine	Oral and parenteral
Naloxone	Parenteral
Omeprazole	Oral
Omeprazole sodium	Parenteral
Ondansetron Hydrochloride	Oral and parenteral
Oxbuprocaine hydrochloride	Ophthalmic
Pentastarch	Parenteral
Prilocaine	External and parenteral
Prochlorperazine mesilate	Oral and rectal
Prochlorperazine maleate	Oral, rectal and buccal
Proxymetacaine hydrochloride	Ophthalmic
Reteplase	Parenteral
Sodium chloride 0.9%	Parental, for reconstitution of injections and for the purpose of cannulae flushing
Sodium chloride 0.9% & Glucose 5% ready made infusion bag	Parenteral
Sodium chloride 0.45% & Glucose 5% ready made infusion bag	Parenteral
Sodium chloride 0.9% with Potassium (K ⁺ 40 mmol/L) ready made infusion bag	Parenteral
Sodium chloride 0.45% and Glucose 5% with Potassium 20mmol per 500 ml ready made infusion bag	Parenteral
Streptokinase	Parenteral
Tacalcitol	External

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<i>Column 1</i>	<i>Column 2</i>
Tenecteplase	Parenteral
Tetanus immunoglobulin	Parenteral
Tetracaine	External
Tinzaparin sodium	Parenteral
Tropicamide	Ophthalmic
Tropisetron hydrochloride	Parenteral
Unfractionated Heparin	Parenteral
Vaccine – Combined Tetanus, diphtheria, acellular pertussis, inactivated poliomyelitis and haemophilus influenza type B	Parenteral
Vaccine – Inactivated Poliomyelitis	Parenteral
Vaccine – Meningococcal Polysaccharide A, C, W135 and Y	Parenteral

- (b) in the entry for “Beclometasone dipropionate”, in column 2, after “nasal” add “inhalation”;
- (c) in the entry for “Budesonide”, in column 2, after “Nasal” add “inhalation”;
- (d) omit the entry for “Cyclizine”;
- (e) in the entry for “Diazepam”(16), in column 2, omit “in palliative care”;
- (f) in the entry for “Diclofenac sodium”(17), in column 2, after “oral” omit “or” and after “rectal” add “or ophthalmic”;
- (g) in the entry for “Domperidone”, in column 2, omit “in palliative care”;
- (h) in the entry for “Domperidone maleate”, in column 2, omit “in palliative care”;
- (i) in the entry for “Flucloxacillin sodium”, in column 2, after “oral” add “or parenteral”;
- (j) in the entry for “Hydrocortisone sodium succinate”, in column 2, after “lozenges” add “or parenteral”;
- (k) in the entry for “Ipratropium bromide”, in column 2, after “nasal” add “inhalation”;
- (l) in the entry for “Lorazepam”(18), in column 2, omit “in palliative care”;
- (m) in the entry for “metoclopramide hydrochloride”, in column 2, omit “in palliative care”;
- (n) in the entry for “Midazolam”(19), in column 2, omit “in palliative care”;
- (o) in the entry for “Ranitidine hydrochloride”, in column 2, after “Oral” insert “or parenteral”.

Amendment of Schedule 5 of the POM Order

8. In the table in Schedule 5 to the POM Order (exemption from restrictions on sale or supply), in paragraph 5 of Part I, in column 2, in sub-paragraph (c)—

- (a) omit “Atropine sulphate”, “Bethanecol chloride”, and “Carbachol”;
- (b) after “Cyclopentolate hydrochloride” insert “Fusidic Acid”; and

(16) The entry for “Diazepam” was inserted by S.I. 2003/2915.

(17) The entry for “Diclofenac Sodium” was inserted by S.I. 2004/2.

(18) The entry for “Lorazepam” was inserted by S.I. 2003/2915.

(19) The entry for “Midazolam” was inserted by S.I. 2003/2915.

- (c) omit “Homatrophine hydrobromide”, “Naphazoline hydrochloride”, “Naphazoline Nitrate”, “Physostigmine salicylate”, “Philocarpine hydrochloride”, and Philocarpine nitrate”.

Signed by authority of the Secretary of State for Health

16th March 2005

Warner
Parliamentary Under Secretary of State,
Department of Health

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

15th March 2005

Deirdre Kenny
A Senior Officer of the,
Department of Health, Social Services and
Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development

15th March 2005

Gerald Lavery
A Senior Officer of the
Department of Agriculture and Rural
Development

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EXPLANATORY NOTE

(This note is not part of the Regulations)

Article 2 of this Order creates a new exemption to 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.

The remainder of this Order further 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 chiropodists and podiatrists, physiotherapists and diagnostic or therapeutic radiographers.

Article 4 amends article 3B of the POM Order to remove the restriction in sub-paragraph (3)(b) of that article which provides that supplementary prescribers may only prescribe prescription only medicines in respect of which a product licence, marketing authorisation or homeopathic certificate of registration is in place, or other prescription only medicines only where the medicine is to be administered in the course of a clinical trial.

Article 5 amends article 13A of the POM Order. Paragraph (1) of article 13A provides that the restrictions on sale or supply of prescription only medicines shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by person of a type listed in the paragraph where the listed person is not, but the pharmacist on reasonable grounds believes him to be, an appropriate practitioner in relation to that medicine. The listed persons are those professionals who may be supplementary prescribers. To accord with the amendments to the revised definition of “supplementary prescriber”, this amendment adds chiropodists and podiatrists, physiotherapists and diagnostic or therapeutic radiographers to that list.

Article 6 substitutes a new Article 15 of the POM Order. Article 15 was amended by the Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001⁽²⁰⁾. Paragraph 2 of the new Article replicates existing provisions. Paragraphs 3 and 4 of the new Article substitutes new provisions which provide that a prescription, other than one given by a veterinary surgeon or practitioner, or for a controlled drug specified in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations, does not have to be signed and written in ink if it is created in electronic form and signed with an advanced electronic signature and transferred to the person by whom it is dispensed as an electronic communication.

Article 7 makes changes to the list of prescription only medicines, in Schedule 3A of the principal Order, which may be prescribed by extended formulary nurse prescribers.

Article 8 makes changes to the list of prescription only medicines which may be sold or supplied by a registered pharmacist on receipt of an order signed by a registered ophthalmic optician, or which may be sold or supplied by a registered ophthalmic optician directly in the course of his professional practice in an emergency.

⁽²⁰⁾ S.I. 2001/2889.

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Three Regulatory Impact Assessments in relation to measures in this Order have 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.