

2006 No. 2807

MEDICINES

The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006

<i>Made</i> - - - -	<i>19th October 2006</i>
<i>Laid before Parliament</i>	<i>26th October 2006</i>
<i>Coming into force</i> - -	<i>17th November 2006</i>

The Secretary of State 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(4) and (5) and 129(4) of the Medicines Act 1968(a), or, in the case of the Department, the powers conferred by those provisions and now vested in it(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 Commission on Human Medicines(c).

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 and shall come into force on 17th November 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 Ministers”, which is relevant to the powers being exercised in the making of this Order, is defined in section 1 of the Act as amended by Schedule 1 to S.I. 1969/388, paragraph 1(1) of the Schedule to S.I. 1999/3142 and paragraph 2 of Part 1 of Schedule 8 to S.I. 2006/2407; section 57(1) of that Act was amended by paragraph 28(1) of Schedule 8 to S.I. 2006/2407; 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 paragraph 2 of Schedule 5 to S.I. 2002/253, by paragraph 10 of Schedule 1 to S.I. 2005/1094 and by paragraph 29 of Part 1 of Schedule 8 to S.I. 2006/2407.
- (b) 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) The expression “the appropriate committee”, referred to in section 58(6) of the Act, is defined in section 4(6) of the Act, as amended by S.I. 2005/1094.
- (d) S.I. 1997/1830; relevant amending instruments are S.I. 1998/108 and 2081, 2003/1590 and 2004/2693.
- (e) S.I. 1980/1924; relevant amending instruments are S.I. 1982/27, 1998/107 and 2005/766.

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 “inhaler”, insert the following definition—

““IRME practitioner” means, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000(a);”;
- (b) after the definition of “maximum strength”, insert the following definition—

““medical exposure” has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;”;
- (c) in the definition of “medicinal product”, omit the words from “, but does not include” to the end;
- (d) for the definition of “operator”, substitute the following definition—

““operator”—

 - (a) in relation to an aircraft, means the person for the time being having management of the aircraft, and
 - (b) for the purposes of article 7B, has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;”;
- (e) after the definition of “prolonged release”, insert the following definition—

““radioactive medicinal product” means a medicinal product which is, which contains or which generates a radioactive substance and which is, contains or generates that substance in order, when administered, to utilize the radiation emitted therefrom;”.

Insertion of article 7B of the POM Order

3. After article 7A of the POM Order insert the following article—

“Exemption for administration by operators

7B.—(1) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to—

- (a) a radioactive medicinal product, administration of which results in a medical exposure; or
- (b) any other prescription only medicine if it is being administered in connection with a medical exposure,

where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to in paragraph (1) are that—

- (a) the radioactive medicinal product or other prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000 which apply to the exposure referred to in paragraph (1);
- (b) that medical exposure has been authorised by an IRME practitioner or, where it is not practicable for an IRME practitioner to authorise the exposure, by an operator acting in accordance with written guidelines issued by an IRME practitioner;
- (c) the IRME practitioner is the holder of a certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978(b);

(a) S.I. 2000/1059, amended by S.I. 2004/1031 and 2006/2523.

(b) S.I. 1978/1006, amended by S.I. 1995/2147 and 2005/2754.

- (d) the radioactive medicinal product or other prescription only medicine is not a controlled drug; and
- (e) in the case of a prescription only medicine which is not a radioactive medicinal product, it is specified in the protocols referred to in sub-paragraph (a).”

Amendment of Schedule 5 to the POM Order

4.—(1) Schedule 5 to the POM Order (exemption for certain persons from section 58(2) of the Act) is amended as follows.

(2) In Part I (exemption from restrictions on sale or supply)—

(a) in column 1 (persons exempted), for paragraph 10 substitute the following paragraph—

“10. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.”; and

(b) in column 2 (prescription only medicines to which the exemption applies), in paragraph 10—

- (i) in sub-paragraph (c), after “volume;” omit “and”,
- (ii) in sub-paragraph (d), for “in weight.” substitute “in weight; and”, and
- (iii) at the end, add—
 - “(e) Amoxicillin;
 - (f) Erythromycin;
 - (g) Flucoxacillin;
 - (h) Tioconazole 28%; and
 - (i) Silver Sulfadiazine.”

(3) In Part II (exemptions from the restriction on supply), after paragraph 7 insert—

<p>“8 Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.</p>	<p>8 Prescription only medicines supplied to a person specified in column 1 in response to an order in writing signed by a doctor.</p>	<p>8 The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.”.</p>
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(4) In Part III (exemptions from restriction on administration)—

(a) in column 1 (persons exempted), for paragraph 1 substitute the following paragraph—

“1. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.”; and

(b) in column 2 (prescription only medicines to which the exemption applies), in paragraph 1, insert at the appropriate place in the alphabetical order of entries as they appear in that paragraph—

“Adrenaline
 Levobupivacaine hydrochloride
 Methylprednisolone
 Ropivacaine hydrochloride”.

Amendment of Schedule 1 to the Pharmacy and General Sale Order

5.—(1) Schedule 1 to the Pharmacy and General Sale Order (exemptions for certain persons from sections 52 and 53) is amended as follows.

(2) In Part I—

(a) in column 1 (persons exempted)—

(i) in paragraph 1, for “State registered” substitute “Registered”, and

(ii) for paragraph 1A substitute the following paragraph—

“1A. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.”; and

(b) in column 2 (medicinal products to which the exemption applies)—

(i) in paragraph 1, in sub-paragraph (c)—

(aa) after “Glutaraldehyde” insert “1.0 per cent Griseofulvin”, and

(bb) after “acid” insert “1.0 per cent Terbinafine”, and

(ii) in paragraph 1A(a)—

(aa) after “volume;” omit “and”, and

(bb) after “1 per cent by weight in weight;” insert—

“(v) Amoxicillin;

(vi) Erythromycin;

(vii) Flucoxacillin;

(viii) Tioconazole 28%; and

(ix) Silver Sulfadiazine;”.

(3) In Part II, after paragraph 14 insert—

“ 15. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.

15. All pharmacy medicines, all medicinal products on a general sale list and prescription only medicines which are sold or supplied to a person specified in column 1 of this paragraph in response to an order in writing signed by a doctor.

15. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.”.

Signed by authority of the Secretary of State for Health

17th October 2006

Andy Burnham
Minister of State,
Department of Health

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

19th October 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 administration and sale or supply of medicines.

Articles 2 to 4 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.

Article 2 amends article 1 of the POM Order and article 3 inserts a new article 7B in order to create an exemption from the requirement that a prescription only medicine may only be administered by an appropriate practitioner or a person acting in accordance with his directions. In particular article 3 makes provision for persons who are operators under the Ionising Radiation (Medical Exposure) Regulations 2000 (“the IRME Regulations”) to administer radioactive medicinal products or other prescription only medicines administered in connection with medical exposures under those Regulations. The operator must be acting in accordance with the relevant procedures and protocols under the IRME Regulations. In addition, the operator must be acting under the authorisation of, or in accordance with the written guidelines of, a person who is a practitioner under the IRME Regulations and the holder of a certificate under the Medicines (Administration of Radioactive Substances) Regulations 1978.

Article 2(c) makes an amendment to the definition of “medicinal product” consequential on the amendments made to the Medicines Act 1968 by Schedule 8 to the Veterinary Medicines Regulations 2006(a). Those Regulations amend the Act so that it no longer applies to veterinary medicinal products.

Article 4(2) and (4) amends Parts I and III of Schedule 5 to the POM Order (exemption for certain persons from section 58(2) of the Act) to extend the list of prescription only medicines which may be sold or supplied or administered by chiropractors and podiatrists in the course of their professional practice.

Articles 4(3) and 5(3) amend Part II of Schedule 5 to the POM Order and Part II of Schedule 1 to the Medicines (Pharmacy and General Sale—Exemption) Order 1980 (“the Pharmacy and General Sale Order”), respectively. These articles create exemptions for persons holding a certificate in first aid from the Mountain Rescue Council of England and Wales or the Northern Ireland Rescue Co-ordinating Committee, to enable them to supply pharmacy and general sale list medicines or prescription only medicines for the treatment of sick or injured persons.

Article 5(2) amends Part I of Schedule 1 to the Pharmacy and General Sale Order which provides exemptions from sections 52 and 53 of the Medicines Act 1968 (restrictions on sale or supply of medicinal products). Article 5(2) extends the list of medicines which may be sold or supplied by chiropractors and podiatrists in the course of their professional practice.

Articles 4(2)(a) and (4)(a) and 5(2) also make amendments consequential on earlier amending Orders.

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.

(a) S.I. 2006/2407.

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