STATUTORY INSTRUMENTS

2004 No. 2693

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004

Made - - - -	*18th October 2004*
Laid before Parliament	*29th October 2004*
Coming into force - -	*19th November 2004*

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 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 and interpretation

1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Amendment (No.3) Order 2004 and shall come into force on 19th November 2004.

(2) In this Order, "the principal Order" means the Prescription Only Medicines (Human Use) Order 1997(**3**).

(**1**) 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, 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).

(**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, by virtue of the powers vested in the Minister 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).

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

Amendment of article 1 of the principal Order

2. In article 1 of the principal Order (interpretation), in paragraph (2), after the definition of "inhaler" insert the following definition—

> ""Local Health Board" has the same meaning as in the National Health Service Act 1977(**4**);".

Amendment of article 7 of the principal Order

3. In article 7 of the principal Order (exemption for parenteral administration in an emergency to human beings of certain prescription only medicines), in the list insert, in the appropriate alphabetical place, each of the following entries—

"Atropine sulphate and obidoxime chloride injection";

"Atropine sulphate and pralidoxime chloride injection";

"Atropine sulphate, pralidoxime mesilate and avizafone injection";

"Pralidoxime chloride injection"; and

"Pralidoxime mesilate injection".

Insertion of article 7A of the principal Order

4. After article 7 of the principal Order, insert the following article—

"**Exemptions for administration of smallpox vaccine**

7A.—(1) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of smallpox vaccine where the conditions specified in paragraph (2) or (3) are satisfied.

(2) The conditions referred to in this paragraph are—

(a) the vaccine has been supplied by, or on behalf of, or under arrangements made by—

(i) the Secretary of State,

(ii) the Scottish Ministers,

(iii) the National Assembly for Wales,

(iv) the Department of Health, Social Services and Public Safety,

(v) an NHS body; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom.

(3) The conditions referred to in this paragraph are—

(a) the vaccine has been supplied by, or on behalf of, or under arrangements made by Her Majesty's Forces;

(b) the vaccine is administered for the purpose of providing protection against smallpox virus to—

(i) members of Her Majesty's Forces; or

(ii) other persons employed or engaged by those Forces.

(**4**) section 16BA of that Act, which makes provision for the establishment of Local Health Boards, was inserted by section 6 of the National Health Service Reform and Healthcare Professions Act 2002 (c. 17).

(4) For the purposes of this regulation, "NHS body" means—

(a) the Common Services Agency,

(b) a Strategic Health Authority, Health Authority or Special Health Authority,

(c) a Primary Care Trust,

(d) a Local Health Board, or

(e) an NHS trust or NHS foundation trust".

Amendment of Schedule 3A to the principal Order

5. In the table in Schedule 3A to the principal Order(**5**) (substances which may be prescribed, administered or directed for administration by extended formulary nurse prescribers and conditions for such prescription or administration)—

(a) in the entry for "Amitriptyline Hydrochloride", in column 2, after "Oral" insert "administration in palliative care";

(b) in the entry for "Carbamazepine", in column 2, after "Oral or rectal" insert "administration in palliative care";

(c) in the entry for "Gabapentin", in column 2, after "Oral" insert "administration in palliative care";

(d) in the entry for "Imipramine hydrochloride", in column 2, after "Oral" insert "administration in palliative care"; and

(e) in the entry for "Nortriptyline hydrochloride", in column 2, after "Oral" insert "administration in palliative care".

Amendment of Schedule 5 to the principal Order

6. In Schedule 5 to the principal Order (exemption for certain persons from section 58(2) of the Medicines Act 1968), in paragraph 9 of Part III, in column 2, in sub-paragraph (c), after the entry for "Adrenaline Acid Tartrate" insert the following entry—

"Amiodarone".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

13th October 2004

(**5**) Schedule 3A was inserted by SI 2002/549, and amended by SI 2003/696 and 2915, and 2004/2 and 1189.

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

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

18th October 2004

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order") which specifies the description and classes of medicines ("prescription only medicines") which, subject to exemptions specified in the Order, 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 2 amends article 1 of the principal Order so as to add a definition of "Local Health Board", a type of NHS body established in Wales.

Article 3 amends article 7 of the principal Order so as to extend the exemption for administration for the purposes of saving life in an emergency to the following medicinal products—

Atropine sulphate and obidoxime chloride injection

Atropine sulphate and pralidoxime chloride injection

Atropine sulphate, pralidoxime mesilate and avizafone injection

Pralidoxime chloride injection

Pralidoxime mesilate injection.

Article 4 inserts a new article 7A of the principal Order so as to create an exemption where smallpox vaccine is administered for the purposes of providing protection in the event of a confirmed or suspected case of smallpox, or where the vaccine is administered to members of, or persons working for, Her Majesty's Forces.

Article 5 amends Schedule 3A to the principal Order so as to provide that certain substances may be prescribed or administered by an extended formulary nurse prescriber only if administered in the course of providing palliative care.

Article 6 amends Part III of Schedule 5 of the principal Order so as to as add amiodarone to the list of substances that may be parenterally administered by paramedics for the immediate, necessary treatment of sick or injured persons.

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.