

2004 No.1189

MEDICINES

**The Prescription Only Medicines (Human Use) Amendment (No. 2)
Order 2004**

<i>Made</i> - - - -	<i>22nd April 2004</i>
<i>Laid before Parliament</i>	<i>27th April 2004</i>
<i>Coming into force</i> - -	<i>18th May 2004</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 58(1), (1B), (4), (4A), (4B) and (5) and 129(4) of the Medicines Act 1968(a), or, as the case may be, those 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, 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. 2) Order 2004 and shall come into force on 18th May 2004.

(2) In this Order, “the principal Order” means the Prescription Only Medicines (Human Use) Order 1997(c).

Amendment of article 1 of the principal Order

2. In article 1(2) of the principal Order (interpretation), in the appropriate alphabetical place, insert the following definitions—

““registered dietitian” means a person who is registered in Part 4 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001(d);”;

““registered occupational therapist” means a person who is registered in Part 6 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;”;

(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, 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).

(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 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).

(c) S.I. 1997/1830; relevant amending instruments are S.I. 2000/1917, 2002/549, 2003/696 and 2915 and 2004/2.

(d) S.I. 2002/254.

““registered orthotist and prosthetist” means a person who is registered in Part 10 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;”;
and

““registered speech and language therapist” means a person who is registered in Part 12 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;”.

Amendment of Schedule 3A to the principal Order

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

- (a) for the entry “Clavulanic acid”, in column 1 add “(as potassium clavulanate)” after “Clavulanic acid”;
- (b) for the entry “Hydrocortisone acetate”, in column 2 add “or aural” after “External use”;
- (c) for the entry “hyoscine butylbromide”, in column 2 omit “or transdermal” after “Parenteral”; and
- (d) 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>
Hyoscine	Transdermal administration in palliative care

Amendment of Schedule 5 to the principal Order

4. In Schedule 5 to the principal Order (exemption for certain persons from section 58(2) of the Medicines Act 1968), in the list in column 2 of entry 9 of Part III, at the appropriate alphabetical place, insert the following entries—

- “Reteplase”; and
- “Tenecteplase”.

Amendment of Schedule 7 to the principal Order

5. In Schedule 7 to the principal Order(b) (classes of individual by whom prescription only medicines may be supplied or administered), at the end of the list in Part III add—

- “Registered dietitians.”;
- “Registered occupational therapists.”;
- “Registered orthotists and prosthetists.”; and
- “Registered speech and language therapists.”

Signed by authority of the Secretary of State for Health

21st April 2004

Warner
Parliamentary Under Secretary of State,
Department of Health

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

22nd April 2004

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

(a) Schedule 3A was inserted by S.I. 2002/549, and amended by S.I. 2003/696, 2003/ 2915 and 2004/2.
(b) Schedule 7 was inserted by S.I.2000/1917, and amended by S.I. 2000/2899 and 2003/1590.

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 3 amends Schedule 3A to the principal Order so as to change the permitted use or route of administration for the following substances, when prescribed or administered by an extended formulary nurse prescriber: hydrocortisone acetate (to include aural use) and hyoscine butylbromide (to remove transdermal administration). Article 3 also adds hyoscine to the list of substances which may be prescribed by extended formulary nurse prescribers, subject to certain conditions. Finally, article 3 amends the reference to the substance clavulanic acid to clavulanic acid (as potassium clavulanate). These changes involve minor corrections to entries inserted by previous orders.

Article 4 amends Part III of Schedule 5 of the principal Order so as to add reteplase and tenecteplase to the list of substances that may be parenterally administered by registered paramedics or persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State.

Article 5 amends Part III of Schedule 7 to the principal Order by adding registered dietitians, occupational therapists, orthotists and prothetists and language and speech therapists to the list of classes of individuals who can supply or administer a prescription only medicine under a Patient Group Direction.

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, Information Centre, Room 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ and a copy has been placed in the libraries of both Houses of Parliament.

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