STATUTORY INSTRUMENTS

2004 No. 2

MEDICINES

The Prescription Only Medicines (Human Use) Amendment Order 2004

Made - - - -	*6th January 2004*
Laid before Parliament	*9th January 2004*
Coming into force - -	*31st January 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), (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, 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 Order 2004 and shall come into force on 31st January 2004.

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

Amendment to article 12 of the principal Order

2. For article 12 of the principal Order(**d**), there is substituted—

(**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 for 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 and 2003/696 and 2915.

(**d**) Article 12 was substituted by SI 2000/1917.

"Exemption for sale and supply in hospitals

12.—(1) Subject to paragraph (3), the restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine in the course of the business of a hospital where the medicine is sold or supplied for the purpose of being administered (whether in the hospital or elsewhere) to a particular person in accordance with directions satisfying the conditions specified in paragraph (2).

(2) The conditions specified in paragraph (1) are that the directions—

(a) are in writing;

(b) relate to the particular person to whom the medicine is to be administered; and

(c) are given by a person (other than a veterinary surgeon or veterinary practitioner) who is an appropriate practitioner in relation to that medicine.

(3) Such directions may be given by an extended formulary nurse prescriber or a supplementary prescriber only where he complies with any condition as to the cases or circumstances in which he may give a prescription for that medicine specified by virtue of article 3A or 3B, as if the directions are a prescription.

(4) The exemption in paragraph (1) applies notwithstanding that the directions do not satisfy the conditions specified in article 15(2).".

Amendment of Schedule 3A to the principal Order

3. In the table 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)—

(a) for the entry for "Erythromycin", in column 2, after "External Use" insert "or oral";

(b) for the entry "Fusidic acid", in column 2 for "Opthalmic Use" substitute "External Use";

(c) for the entry "Hycosine butylbromide", in column 2, after "parenteral" insert "or transdermal";

(d) for the entry "Hycosine hydrobromide", in column 2, for "Oral, parenteral or transdermal administration in palliative care" substitute "Oral or parenteral administration in palliative care";

(e) for the entry "Metronidazole", in column 2 for "External use or oral" substitute "External use, oral or rectal";

(f) for the entry "Prednisolone sodium phosphate", in column 2, after "Aural" insert "or oral";

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

Column 1	*Column 2*
Amitriptyline hydrochloride	Oral
Azithromycin dihydrate	Oral
Carbamazepine	Oral or rectal
Clavulanic acid	Oral
Conjugated oestrogens (equine)	External use
Diclofenac potassium	Oral
Diclofenac sodium	Oral or rectal
Erythromycin ethyl succinate	Oral
Erythromycin stearate	Oral

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

Estradiol	External use
Estriol	External use
Etonogestrel	Implant
Flumazenil	Parenteral
Gabapentin	Oral
Glucagon hydrochloride	Parenteral
Glucose	Parenteral
Imipramine hydrochloride	Oral
Lignocaine hydrochloride	External use or parenteral
Lymecycline	Oral
Nortriptyline hydrochloride	Oral
Prednisolone	Oral
Salbutamol sulphate	Inhalation
Sodium fusidate	External use
Terbutaline sulphate	Inhalation

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), insert in the list in column 2 of paragraph 2 of Part III, at the appropriate place in the alphabetical order of the entries as they appear in that list, the following entries—

"Diamorphine"

"Morphine".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
31st December 2003 Department of Health

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

D.C. Gowdy
Permanent Secretary,
6th January 2004 Department of Health, Social Services and Public Safety

L.S.

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 substitutes a revised Article 12 of the principal Order, so as to extend the exemption from section 58(2)(a) of the Medicines Act 1968 for the sale or supply of a prescription only medicine in the course of the business of a hospital for the purpose of being administered in accordance with written directions, to cases where the directions are given by any appropriate practitioner (other than veterinary surgeons and veterinary practitioners). It also provides that where conditions apply as to the cases or circumstances in which an extended formulary nurse prescriber or a supplementary prescriber may give a prescription, those conditions also apply in relation to the written directions given by those prescribers in accordance with the exemption.

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: erythromicin (to include oral use), fusidic acid (to extend to all external uses), hycosine butylbromide (to include transdermal administration), hycosine hydrobromide (to remove transdermal administration), metronidazole (to include rectal administration), prednisolone sodium phosphate (to include oral use). Article 3 also adds to the list of substances which may be prescribed by extended formulary nurse prescribers, subject to certain conditions, the following substances: amitriptyline hydrochloride, azithromycin dihydrate, carbamazepine, clavulanic acid, conjugated oestrogens (equine), diclofenac potassium, diclofenac sodium, erythromycin ethyl succinate, erythromycin stearate, estradiol, estriol, etonogestrel, flumazenil, gabapentin, glucagon hydrochloride, glucose, imipramine hydrochloride, lignocaine hydrochloride, lymecycline, nortriptyline hydrochloride, prednisolone, salbutamol sulphate, sodium fusidate, terbutaline sulphate.

Article 4 amends Part III of Schedule 5 of the principal Order so as to add diamorphine and morphine to the list of substances that may be parenterally administered by registered midwives.

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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