STATUTORY INSTRUMENTS

2002 No. 549

MEDICINES

The Prescription Only Medicines (Human Use) Amendment Order 2002

Made - - - -	*7th March 2002*
Laid before Parliament	*11th March 2002*
Coming into force - -	*1st April 2002*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Minister of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by sections 58(1), (4), (4A) and (5), 59, 103(2) and 129(4) of the Medicines Act 1968(**1**), or, as the case may be, those 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 the 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 2002 and shall come into force on 1st April 2002.

(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, and by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; 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 the Schedule to, S.I. 1999/3142; and in the case of the Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**3**) S.I. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2899 and 3231, and 2001/2777, 2889 and 3942.

Amendment of article 1 of the principal Order

2.—(1) Article 1 of the principal Order (citation, commencement and interpretation) is amended as follows.

(2) In paragraph (1)—

(a) omit the definition of "appropriate nurse practitioner";

(b) after the definition of "cyanogenetic substances" insert the following definition—

""district nurse/health visitor prescriber" means—

(a) a person who—

(i) is registered in Part 1 or 12 of the professional register, and

(ii) has a district nursing qualification additionally recorded in the professional register under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983(**4**); or

(b) a person who is registered in Part 11 of the professional register as a health visitor,

against whose name (in each case) is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances for patients;";

(c) after the definition of "dosage unit" insert the following definitions—

""Extended Formulary" means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary;

"extended formulary nurse prescriber" means a person—

(a) who is registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register; and

(b) against whose name is recorded in that register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Extended Formulary;";

(d) in the definition of "health prescription", for "or nurse prescriber" insert ", a district nurse/health visitor prescriber or an extended formulary nurse prescriber";

(e) after the definition of "Primary Care Trust"(**5**) insert the following definition—

""professional register" means the register maintained by the Nursing and Midwifery Council(**6**) pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(**7**);";

(f) in the definition of "registered midwife", for the words from "the Register" to the end substitute "the professional register";

(g) in the definition of "registered nurse", for the words from "the Register" to the end substitute "the professional register";

(h) in the definition of "state registered chiropodist", for the words from "the Register" to the end substitute "the register of chiropodists maintained by the Health Professions Council(**8**) pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001(**9**)"; and

(**4**) The rules were approved by S.I. 1983/873; there are amendments to the rules which are not relevant to this Order.
(**5**) Inserted by article 2(a) of S.I. 2000/1917.
(**6**) *See* article 3 of the Nursing and Midwifery Order 2001, S.I. 2002/253.
(**7**) S.I. 2002/253.
(**8**) *See* article 3 of the Health Professions Order 2001, S.I. 2002/254.
(**9**) S.I. 2002/254.

(i) in the definition of "state registered paramedic", for the words from "the Register" to the end substitute "the register of paramedics maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001".

(3) In paragraph (5)(**10**), for "Schedules 1, 2 and 5" substitute "Schedules 1, 2, 3A and 5".

Amendment of article 2 of the principal Order

3. In article 2 of the principal Order (appropriate practitioners), for paragraph (b) substitute the following paragraphs—

"(b) in relation to the descriptions and classes of medicinal products specified in Schedule 3, district nurse/health visitor prescribers;

(c) in relation to the descriptions and classes of medicinal products specified in article 3A(1), extended formulary nurse prescribers.".

Amendment of article 3 of the principal Order

4. For article 3 of the principal Order (which specifies classes of prescription only medicines), substitute the following article—

"**Medicinal products on prescription only**

3. The following descriptions and classes of medicinal products are specified for the purposes of section 58, namely—

(a) medicinal products in respect of which a marketing authorization has been granted, which in the marketing authorization are classified as being prescription only medicines;

(b) medicinal products in respect of which no marketing authorization has been granted consisting of or containing a substance listed in column 1 of Schedule 1;

(c) medicinal products that are for parenteral administration;

(d) medicinal products that are controlled drugs unless a marketing authorization has been granted in respect of that medicinal product in which the product is classified as being a pharmacy only or on general sale list medicine;

(e) cyanogenetic substances, other than preparations for external use;

(f) medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used.".

Insertion of article 3A in the principal Order

5. After article 3 of the principal Order, insert the following article—

"**Prescribing by extended formulary nurse prescribers**

3A.—(1) Subject to paragraph (2), the description and classes of medicinal products in relation to which extended formulary nurse prescribers are appropriate practitioners are those prescription only medicines which consist of, or contain, one or more of the substances specified in column 1 of Schedule 3A, but which do not contain any other substance or combination of substances which is a prescription only medicine not included in Schedule 3A.

(**10**) Paragraph (5) was amended by article 2 of S.I. 2001/2777.

(2) An extended formulary nurse prescriber may—

(a) give a prescription for a medicinal product referred to in paragraph (1); or

(b) if that medicinal product is for parenteral administration—

(i) administer that medicinal product, or

(ii) give directions for the administration of that medicinal product,

only where he complies with any condition as to the cases or circumstances in which he may do so that is specified by virtue of paragraph (3).

(3) If the entry in column 2 of Schedule 3A relating to a substance specifies one or more requirements as to use, route of administration or pharmaceutical form, it is a condition for the purposes of paragraph (2) that a medicinal product which consists of, or contains, that substance is administered, or is prescribed or directed for administration, in accordance with the specified requirements.".

Amendment of article 8 of the principal Order

6. Article 8 of the principal Order (exemptions for emergency sale or supply) is amended as follows—

(a) in paragraph (2)—

(i) in sub-paragraph (a), after "doctor" insert ", a district nurse/health visitor prescriber or an extended formulary nurse prescriber";

(ii) in sub-paragraph (b), after "doctor" insert ", district nurse/health visitor prescriber or extended formulary nurse prescriber";

(iii) in sub-paragraph (c), after "doctor" insert ", district nurse/health visitor prescriber or extended formulary nurse prescriber"; and

(b) in paragraph (4), in sub-paragraph (a), in head (ii), after "doctor" insert ", district nurse/health visitor prescriber or extended formulary nurse prescriber".

Insertion of article 13A into the principal Order

7. After article 13 of the principal Order (exemption in cases involving another's default) insert the following article—

"**Exemptions relating to prescriptions given by nurses**

13A.—(1) 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 by a pharmacist in accordance with a prescription given by a registered nurse or registered midwife who is not an appropriate practitioner in relation to that medicine where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.

(2) 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 by a pharmacist in accordance with a prescription given by an extended formulary nurse prescriber where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the extended formulary nurse prescriber has complied with any condition with which he is required to comply by virtue of article 3A(2) and (3).".

Amendment of article 15 of the principal Order

8. In article 15 (prescriptions)(**11**), in paragraph (2)(c)—

(a) in head (iii), for "an appropriate nurse practitioner" substitute "a district nurse/health visitor prescriber, an extended formulary nurse prescriber"; and

(b) in head (iv), for "or appropriate nurse practitioner" substitute ", a district nurse/health visitor prescriber or an extended formulary nurse prescriber".

Insertion of Schedule 3A in the principal Order

9. After Schedule 3 to the principal Order, insert the following Schedule—

"SCHEDULE 3A Article 3A

SUBSTANCES WHICH MAY BE PRESCRIBED, ADMINISTERED OR DIRECTED FOR ADMINISTRATION BY EXTENDED FORMULARY NURSE PRESCRIBERS AND CONDITIONS FOR SUCH PRESCRIPTION OR ADMINISTRATION

Column 1 *Substance*	*Column 2* *Requirements as to use, route of administration, or pharmaceutical form*
Aciclovir	External use
Acrivastine	Oral
Adapalene	External use
Alclometasone dipropionate	External use
Alimemazine tartrate (trimeprazine tartrate)	Oral
Amorolfine hydrochloride	External use
Amoxycillin trihydrate	Oral
Aspirin	Oral
Azelaic acid	External use
Azelastine hydrochloride	Ophthalmic use or nasal
Baclofen	Oral administration in palliative care
Beclometasone dipropionate	External use or nasal
Betamethasone dipropionate	External use
Betamethasone sodium phosphate	Aural or nasal
Betamethasone valerate	External use
Budesonide	Nasal
Carbaryl	External use
Carbenoxolone sodium	Mouthwash
Cetirizine hydrochloride	Oral
Chloramphenicol	Ophthalmic use

(**11**) Article 15 was amended by S.I. 2001/2889.

Column 1 *Substance*	*Column 2* *Requirements as to use, route of administration, or pharmaceutical form*
Cimetidine	Oral
Cinchocaine hydrochloride	External use
Clindamycin phosphate	External use
Clobetasone butyrate	External use
Clotrimazole	External use
Cyclizine	Parenteral administration in palliative care
Dantrolene sodium	Oral administration in palliative care
Dantron	Oral
Desogestrel	Oral
Desoximetasone (Desoxymethasone)	External use
Dexamethasone	Aural
Dexamethasone isonicotinate	Nasal
Diclofenac diethylammonium	External use
Domperidone	Oral or rectal administration in palliative care
Domperidone maleate	Oral administration in palliative care
Doxycycline	Oral
Econazole nitrate	External use
Erythromycin	External use
Ethinylestradiol	Oral
Etynodiol diacetate (ethynodiol diacetate)	Oral
Famotidine	Oral
Felbinac	External use
Fenticonazole nitrate	External use
Fexofenadine hydrochloride	Oral
Flucloxacillin sodium	Oral
Fluconazole	Oral
Fludroxycortide (Flurandrenolone)	External use
Flumetasone pivalate	Aural
Flunisolide	Nasal
Fluocinolone acetonide	External use
Fluocinonide	External use
Fluocortolone hexanoate	External use
Fluocortolone pivalate	External use

Column 1 *Substance*	*Column 2* *Requirements as to use, route of administration, or pharmaceutical form*
Flurbiprofen	Lozenges
Fluticasone propionate	External use or nasal
Fusidic acid	Ophthalmic use
Gentamicin sulphate	Aural
Gestodene	Oral
Hydrocortisone	External use
Hydrocortisone acetate	External use
Hydrocortisone butyrate	External use
Hydrocortisone sodium succinate	Lozenges
Hyoscine butylbromide	Parenteral administration in palliative care
Hyoscine hydrobromide	Oral, parenteral or transdermal administration in palliative care
Ibuprofen	External use or oral
Ibuprofen lysine	Oral
Ipratropium bromide	Nasal
Isotretinoin	External use
Ketoconazole	External use
Ketoprofen	External use
Levocabastine hydrochloride	Ophthalmic use or nasal
Levomepromazine (methotrimeprazine) maleate	Oral administration in palliative care
Levomepromazine (methotrimeprazine) hydrochloride	Parenteral administration in palliative care
Levonorgestrel	Oral
Lithium succinate	External use
Lodoxamide trometamol	Ophthalmic use
Loperamide hydrochloride	Oral
Loratadine	Oral
Mebendazole	Oral
Medroxyprogesterone acetate	Parenteral
Mestranol	Oral
Metoclopramide hydrochloride	Oral or parenteral administration in palliative care
Metronidazole	External use or oral

Column 1 *Substance*	*Column 2* *Requirements as to use, route of administration, or pharmaceutical form*
Metronidazole benzoate	Oral
Miconazole	Dental lacquer
Miconazole nitrate	External use
Minocycline	Oral
Mometasone furoate	External use or nasal
Nedocromil sodium	Ophthalmic use
Nefopam hydrochloride	Oral
Neomycin sulphate	Aural
Neomycin undecenoate	Aural
Nitrofurantoin	Oral
Nizatidine	Oral
Norethisterone 9	Oral
Norethisterone acetate	Oral
Norethisterone enanthate	Parenteral
Norgestimate	Oral
Norgestrel	Oral
Nystatin	External use
Oxytetracycline dihydrate	Oral
Paracetamol	Oral
Penciclovir	External use
Piroxicam	External use
Prednisolone hexanoate	External use
Prednisolone sodium phosphate	Aural
Ranitidine hydrochloride	Oral
Silver sulphadiazine	External use
Sodium cromoglycate	Ophthalmic use
Streptodornase	External use
Streptokinase	External use
Sulconazole nitrate	External use
Terbinafine hydrochloride	External use
Tetracycline hydrochloride	External use or oral
Tretinoin	External use
Triamcinolone acetonide	External use, aural, nasal or oral paste

Column 1 *Substance*	*Column 2* *Requirements as to use, route of administration, or pharmaceutical form*
Trimethoprim	Oral
Tuberculin PPD	Parenteral
Vaccine, Adsorbed Diphtheria	Parenteral
Vaccine, Adsorbed Diphtheria And Tetanus	Parenteral
Vaccine, Adsorbed Diphtheria And Tetanus For Adults And Adolescents	Parenteral
Vaccine, Adsorbed Diphtheria For Adults And Adolescents	Parenteral
Vaccine, Adsorbed Diphtheria, Tetanus And Pertussis	Parenteral
Vaccine, Adsorbed Diphtheria, Tetanus And Pertussis (Acellular Component)	Parenteral
Vaccine, BCG	Parenteral
Vaccine, BCG Percutaneous	Parenteral
Vaccine, Haemophilus Influenzae Type B (Hib)	Parenteral
Vaccine, Haemophilus Influenzae Type B (Hib) with Diphtheria, Tetanus And Pertussis	Parenteral
Vaccine, Haemophilus Influenzae Type B, Diphtheria, Tetanus And Acellular Pertussis	Parenteral
Vaccine, Hepatitis A	Parenteral
Vaccine, Hepatitis A With Typhoid	Parenteral
Vaccine, Hepatitis A, Inactivated, With Recombinant (DNA) Hepatitis B	Parenteral
Vaccine, Hepatitis B	Parenteral
Vaccine, Influenza	Parenteral
Vaccine, Live Measles, Mumps And Rubella (MMR)	Parenteral
Vaccine, Meningococcal Group C Conjugate	Parenteral
Vaccine, Meningococcal Polysaccharide A and C	Parenteral
Vaccine, Pneumococcal	Parenteral
Vaccine, Poliomyelitis, Inactivated	Parenteral
Vaccine, Poliomyelitis, Live (Oral)	Oral
Vaccine, Rubella, Live	Parenteral
Vaccine, Tetanus, Adsorbed	Parenteral

Column 1 *Substance*	*Column 2* *Requirements as to use, route of administration, or pharmaceutical form*
Vaccine, Typhoid, Live Attenuated (Oral)	Oral
Vaccine, Typhoid, Polysaccharide	Parenteral".

Amendment of Schedule 7 to the principal Order

10. In Part III of Schedule 7 to the principal Order(**12**) (Patient Group Directions—classes of individuals by whom supplies may be made), for the last three entries substitute the following entries—

"Individuals who are registered in the register of orthoptists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered orthoptists).

Individuals who are registered in the register of physiotherapists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered physiotherapists).

Individuals who are registered in the register of radiographers maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered radiographers).".

Revocations

11. Articles 4 and 6 of the principal Order are revoked.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State
Department of Health
7th March 2002

Bairbre de Brún
Minister of Health, Social Services and Public Safety
7th March 2002

(**12**) Schedule 7 was inserted by article 2(e) of S.I. 2000/1917.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order").

Articles 2, 3, 5 and 9 make provision for nurses meeting certain conditions ("extended formulary nurse prescribers") to prescribe certain prescription only medicines. Article 2 amends article 1 of the principal Order, so as to insert definitions of "extended formulary nurse prescriber" and "district nurse/health visitor prescriber", and makes changes consequential on the Nursing and Midwifery Order 2001 (S.I.2002/253). Article 3 amends article 2 of the principal Order, so as to provide that such persons are "appropriate practitioners" for the purposes of section 58 of the Medicines Act 1968 (restrictions on sale and supply), as amended by section 63 of the Health and Social Care Act 2001. Article 5 inserts a new article 3A into that Order, which makes provision for prescribing by extended formulary nurse prescribers; in particular, for the descriptions and classes of product which they may prescribe and the conditions as to the cases or circumstances in which such a person may prescribe. Article 9 inserts Schedule 3A into that Order; the Schedule lists the substances which such persons are able to prescribe and the requirements which must be complied with in relation to each substance. Articles 6 and 8 make consequential amendments.

Articles 2(2)(h) and (i) and 10 make amendments consequential on the Health Professions Order 2001 (S.I. 2002/254), which makes provision for the regulation of certain health professions, including chiropodists, paramedics, orthoptists, physiotherapists and radiographers.

Article 4 amends article 3 of the principal Order (which specifies classes of products which are prescription only medicines) to provide that medicinal products which have been granted a United Kingdom or Community marketing authorization will be prescription only medicines if so classified in their marketing authorization. Medicinal products for which no marketing authorization has been granted will continue to be classified as prescription only if they contain a substance listed in column 1 of Schedule 1. Article 10 revokes articles 4 and 6 of the principal Order as a consequence of these changes.

Article 7 inserts article 13A into the principal Order, which provides for exemptions from the restrictions in section 58 of the 1968 Act (restrictions on sale and supply) in cases where a pharmacist supplies a medicinal product in accordance with a prescription by a nurse or midwife.

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 Control Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.