S T A T U T O R Y I N S T R U M E N T S

2003 No. 696

MEDICINES

The Prescription Only Medicines (Human Use) Amendment Order 2003

Made - - - -	*13th March 2003*
Laid before Parliament	*14th March 2003*
Coming into force	*4th April 2003*

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 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 2003 and shall come into force on 4th April 2003.

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

(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, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2899 and 3231, 2001/2777, 2889 and 3942, and 2002/549 and 2469.

(2) In paragraph (2)—

(a) after the definition of "aerosol", insert the following definitions—

"" "clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates,

(b) the doctor or dentist who is a party to the plan, and

(c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

"clinical trial exemption" means an exemption conferred by—

(a) section 31(5) of the Act,

(b) article 4 of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972**(a)**,

(c) article 2 or 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974**(b)**, or

(d) article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995**(c)**;";

(b) in the definition of "extended formulary nurse prescriber"—

(i) for paragraph (a), substitute the following paragraph—

"(a) who is a first level nurse, and", and

(ii) in paragraph (b), for "that register" substitute "the professional register";

(c) after the definition of "external use", insert the following definition—

"" "first level nurse" means a person registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;";

(d) after the definition of "Health Authority"**(d)**, insert the following definition—

"" "health care" means services for or in connection with the prevention, diagnosis or treatment of disease;";

(e) in the definition of "health prescription", after "dentist" insert ", supplementary prescriber";

(f) after the definition of "health prescription", insert the following definition—

"" "health record" has the meaning given by section 68(2) of the Data Protection Act 1998**(e)**;";

(g) after the definition of "homoeopathic certificate of registration"**(f)**, insert the following definitions—

"" "independent clinic"—

(a) in relation to England and Wales, has the meaning given by section 2(4) of the Care Standards Act 2000**(g)**, and

(b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001**(h)**;

"independent hospital"—

(a) in relation to England and Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000, and

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(a) S.I. 1972/1200.
(b) S.I. 1974/498.
(c) S.I. 1995/2808.
(d) The definition of "Health Authority" was inserted by S.I. 2000/1917.
(e) 1998 c.29.
(f) The definition of "homoeopathic certificate of registration" was inserted by S.I. 2000/1917.
(g) 2000 c.14.
(h) 2001 asp 8.

(b) in relation to Scotland, means—

(i) an independent hospital, or

(ii) a private psychiatric hospital,

as defined by section 77(1) of the Regulation of Care (Scotland) Act 2001;

"independent medical agency"—

(a) in relation to England and Wales, has the meaning given by section 2(5) of the Care Standards Act 2000, and

(b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;";

(h) after the definition of "NHS trust"**(a)**, insert the following definition—

" "nursing home" has the meaning given by article 16 of the Registered Homes (Northern Ireland) Order 1992**(b)**;";

(i) after the definition of "Primary Care Trust"**(c)**, insert the following definition—

" "prison service" means—

(a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952**(d)**),

(b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989**(e)**), and

(c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953**(f)**);";

(j) after the definition of "registered ophthalmic optician", insert the following definition—

" "registered provider" means—

(a) in relation to an independent hospital, an independent clinic or an independent medical agency—

(i) in relation to England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the person carrying on the establishment or agency,

(ii) in relation to Scotland, the person who is registered under Part 1 of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency, and

(b) in relation to a nursing home, the person registered under Part III of the Registered Homes (Northern Ireland) Order 1992 as the person carrying on the nursing home, other than a manager who is to be treated as carrying on the home by virtue of article 17(2) of that order;

"relevant manager" means—

(a) in relation to an independent hospital, an independent clinic or an independent medical agency—

(i) in relation to England and Wales—

(aa) a person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or

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(a) The definition of "NHS trust" was inserted by S.I. 2000/1917.
(b) S.I. 1992/3204 (N.I. 20).
(c) The definition of "Primary Care Trust" was inserted by S.I. 2000/1917.
(d) 1952 c.52.
(e) 1989 c.45.
(f) 1953 (c.18 (N.I.)).

(bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person,

(ii) in relation to Scotland, a person, other than the registered provider, who was identified as an individual who is to manage the establishment or agency on the application for registration of that establishment or agency under Part 1 of Regulation of Care (Scotland) Act 2001, and

(b) in relation to a nursing home, the manager of the nursing home, unless they are the registered provider for that home;

"relevant register" means—

(a) in relation to a first level nurse, the professional register, and

(b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954**(a)** or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976**(b)**;"; and

(k) after the definition of "Strategic Health Authority"**(c)**, insert the following definition—

" "supplementary prescriber" means—

(a) a first level nurse, or

(b) a pharmacist,

against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;".

(3) In paragraph (7)**(d)**, for "12C" substitute "12E".

Amendment of article 2 of the principal Order

3. In article 2 of the principal Order (appropriate practitioners), in paragraph (a), after "dentists" insert ", supplementary prescribers".

Amendment of article 3 of the principal Order

4. In article 3 of the principal Order (medicinal products on prescription only), after paragraph (f) add the following paragraph—

"(g) medicinal products in respect of which a marketing authorization has been granted consisting of or containing aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules which in the marketing authorization are classified as being pharmacy only or general sale list medicines.".

Amendment of article 3A of the principal Order

5. In article 3A of the principal Order**(e)**—

(a) at the beginning of paragraph (2), insert "Subject to paragraph (4),"; and

(b) after paragraph (3), add the following paragraph—

"(4) An extended formulary nurse prescriber may prescribe or administer a medicinal product referred to in paragraph (1), or give directions for

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(a) 1954 c.61.
(b) S.I. 1976/1213 (N.I.22).
(c) The definition of "Strategic Health Authority" was inserted by regulation 7 of, and Schedule 4 to, S.I. 2002/2469.
(d) Regulation 1(7) to (9) was inserted by S.I. 2000/1917.
(e) Article 3A was inserted by S.I. 2002/549.

administration of such a product, without complying with any condition specified by virtue of paragraph (3) if—

(a) he is a supplementary prescriber; and

(b) he complies with the applicable conditions set out in article 3B(3).".

Insertion of articles 3B and 3C of the principal Order

6. After article 3A of the principal Order, insert the following articles—

"**Prescribing and administration by supplementary prescribers**

3B.—(1) Subject to paragraph (2), a supplementary prescriber may—

(a) give a prescription for a medicinal product referred to in article 3; 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 the conditions as to the cases or circumstances in which he may do so specified in paragraph (3).

(2) Paragraph (1) does not apply if—

(a) the supplementary prescriber is a district nurse/health visitor prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in Schedule 3; or

(b) the supplementary prescriber is an extended formulary nurse prescriber and—

(i) the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in article 3A(1), and

(ii) he satisfies any applicable condition specified by virtue of article 3A(3).

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

(a) the supplementary prescriber is acting in accordance with the terms of a clinical management plan which—

(i) relates to the patient for whom the product is prescribed or to whom it is, or is to be, administered,

(ii) is in effect at the time the prescription or direction is given or, as the case may be, the product is administered, and

(iii) includes the particulars specified in Schedule 3B;

(b) at the time the prescription or directions are given or, as the case may be, the product is administered—

(i) a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of the product, or

(ii) the product is, or is to be, administered in the course of a clinical trial and—

(a) the trial is the subject of a clinical trial certificate, or

(b) a clinical trial exemption has effect in relation to the supply of the product for the purposes of the trial; and

(c) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan.

Exemptions from conditions in respect of the cases or circumstances in which an extended formulary nurse prescriber or supplementary prescriber may administer a medicinal product

3C. The conditions specified by virtue of article 3A(3) and in article 3B(3) shall not apply in relation to the administration of a medicinal product by an extended formulary nurse prescriber or a supplementary prescriber where—

(a) that person is acting in accordance with the directions of another person who is an appropriate practitioner, or

(b) that administration is exempt from the restriction in section 58(2)(b) (restriction on administration) by virtue of any of the subsequent provisions of this Order.".

Insertion of article 5A of the principal Order

7. After article 5 of the principal Order (exempt medicinal products), insert the following article—

"**Exemption for products consisting of or containing aloxiprin, aspirin or paracetamol**

5A. A medicinal product falling within article 3(g) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the quantity of that product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.".

Amendment of article 8 of the principal Order

8. 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 supplementary prescriber",

(ii) in sub-paragraph (b), after "doctor" insert ", supplementary prescriber", and

(iii) in sub-paragraph (c), after "doctor" insert ", supplementary prescriber"; and

(b) in paragraph (4), in sub-paragraph (a), in head (ii), after "doctor" insert ", supplementary prescriber".

Amendment of article 10 of the principal Order

9. Article 10 of the principal Order (exemption for medicinal products at high dilutions) is renumbered as paragraph (1) of that article and after paragraph (1), insert the following paragraph—

"(2) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains solely one or more unit preparations of the following substances—

Aconite

Arsenic Trioxide

Belladonna Herb

Ignatia Bean

Nux Vomica Seed,

if each such unit preparation has been diluted to at least one part in a million (6x)".

Amendment of article 12C of the principal Order

10. In article 12C of the principal Order**(a)** (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)—

(a) Article 12C was inserted by S.I. 2000/1917.

(a) in paragraph (1), for sub-paragraph (a) substitute the following sub-paragraph—

"(a) the medicine is supplied, or as the case may be, is administered by such a person pursuant to an arrangement made with—

(i) a body referred to in article 12A(a) to (d),

(ii) an authority or person carrying on the business of an establishment or agency referred to in article 12D(1),

(iii) a force or service referred to in article 12E(1)(a)(i) to (iii), or

(iv) Her Majesty's Forces,

for the supply or, as the case may be, the administration of prescription only medicines;";

(b) in paragraph (2)—

(i) for sub-paragraph (c), substitute the following sub-paragraph—

"(c) the Patient Group Direction is signed—

(i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,

(ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider and, if there is a relevant manager for the establishment or agency, that manager,

(iii) in the case of an arrangement with a prison service, by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that service,

(iv) in the case of an arrangement with a police force or the Police Service of Northern Ireland—

(a) by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, and

(b) a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland, and

(v) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces;", and

(ii) in sub-paragraph (cc)**(a)**, for "designated in writing" to the end substitute the following—

"designated in writing—

(i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,

(ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider or, if there is a relevant manager for the establishment or agency, that relevant manager,

(iii) in the case of an arrangement with a force or service referred to in article 12E(1)(a)(i) to (iii), by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to

(a) Sub-paragraph (cc) was inserted by S.I. 2000/2899.

this Order against the entry in column 1 of that Table for that force or service, or

(iv) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces,

for the purpose of the administration of prescription only medicines under the Patient Group Direction; and".

Insertion of articles 12D and 12E of the principal Order

11. After article 12C of the principal Order (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction), insert the following articles—

"**Exemption for the supply and administration of prescription only medicines by independent hospitals, clinics and agencies**

12D.—(1) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine in the course of the business of—

(a) in England, Wales or Scotland—

(i) an independent hospital,

(ii) an independent clinic, or

(iii) an independent medical agency; or

(b) in Northern Ireland, a nursing home,

where the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to are that—

(a) the Patient Group Direction relates to the supply or, as the case may be, the administration, by the person who supplies or administers the medicine, of a description or class of prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;

(b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);

(c) the Patient Group Direction is signed—

(i) by or on behalf of the registered provider, and

(ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager;

(d) the individual who supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing—

(i) by or on behalf of the registered provider, or

(ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager,

for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and

(e) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces

12E.—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—

(a) the individual supplies or, as the case may be, administers the medicine in order to assist the provision of health care by, on behalf of, or under arrangements made by—

(i) a police force in England, Wales or Scotland,

(ii) the Police Service of Northern Ireland,

(iii) a prison service, or

(iv) Her Majesty's Forces;

(b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and

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

(2) The conditions referred to are that—

(a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the provision of health care by, or on behalf of, or under arrangements made by the police force or service, the prison service or, as the case may be, Her Majesty's Forces;

(b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;

(c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);

(d) the Patient Group Direction is signed—

(i) by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order ("the authorising person") against the entry in column 1 of that Table for the police force or service, the prison service or Her Majesty's Forces by whom, or on whose behalf, the health care is provided, or with whom arrangements are made for the provision of such care; and

(ii) in the case of a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;

(e) the individual referred to in paragraph (1) is designated in writing, by or on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and

(f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.".

Amendment of article 13A of the principal Order

12. In article 13A of the principal Order (exemption relating to prescriptions given by nurses)**(a)**—

(a) Article 13A was inserted by S.I. 2002/549.

(a) for paragraph (1), substitute—

"(1) The restrictions imposed by section 58(2)(a) (restrictions in 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) another pharmacist,

(b) a registered nurse, or

(c) a registered midwife,

who is not an appropriate practitioner in relation to that medicine where the pharmacist selling or supplying the medicine, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner."; and

(b) in paragraph (2)—

(i) after "extended formulary nurse prescriber", in both places those words appear, insert "or supplementary prescriber", and

(ii) for "article 3A(2) and (3)" substitute "articles 3A(2) and (3) or 3B".

Amendment of article 15 of the principal Order

13. In article 15 (prescriptions)**(a)**, in paragraph (2)(c)—

(a) in head (iii), after "dentist" insert ", a supplementary prescriber"; and

(b) in head (iv), after "dentist" insert ", a supplementary prescriber".

Amendment of Schedule 3 to the principal Order

14. In Schedule 3 to the principal Order (descriptions and classes of prescription only medicines in relation to which appropriate nurse practitioners are appropriate practitioners), at the end insert the following entry—

"Water for Injections".

Amendment of Schedule 3A to the principal Order

15. In the table in Schedule 3A to the Order (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 in column 1 for "Doxycycline", after "Doxycycline" insert "hyclate";

(b) omit the entry for "Vaccine, Poliomyelitis, Inactivated"; and

(c) 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*
Emedastine	Ophthalmic use
Doxycycline monohydrate	Oral
Flucloxacillin magnesium	Oral
Minocycline hydrochloride	Oral
Mizolastine	Oral
Water for Injections	Parenteral

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

Insertion of Schedule 3B of the principal Order

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

"SCHEDULE 3B Regulation 3B(3)(a)(iii)

PARTICULARS FOR CLINICAL MANAGEMENT PLANS

A clinical management plan shall contain the following particulars—

(a) the name of the patient to whom the plan relates;

(b) the illnesses or conditions which may be treated by the supplementary prescriber;

(c) the date on which the plan is to take effect and when it is to be reviewed by the doctor or dentist who is a party to the plan;

(d) reference to the class or description of medicinal product which may be prescribed or administered under the plan;

(e) any restrictions or limitations as to the strength or dose of any product which may be prescribed or administered under the plan, and any period of administration or use of any medicinal product which may be prescribed or administered under the plan;

(f) relevant warnings about the known sensitivities of the patient to, or known difficulties of the patient with, particular medicinal products;

(g) the arrangements for notification of—

(i) suspected or known adverse reactions to any medicinal product which may be prescribed or administered under the plan, and

(ii) suspected or known adverse reactions to any other medicinal product taken at the same time as any medicinal product prescribed or administered under the plan; and

(h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan."

Amendment of Schedule 7 to the principal Order

17. In Schedule 7 to the principal Order**(a)** (Patient Group Directions), after Part II, insert the following Part—

"PART IIA

PERSONS BY WHOM OR ON WHOSE BEHALF A PATIENT GROUP DIRECTION USED IN THE PROVISION OF HEALTH CARE BY OR ON BEHALF OF THE POLICE, THE PRISON SERVICES OR THE ARMED FORCES MUST BE SIGNED

Column 1 **Force or service by whom or on whose behalf the health care is provided**	*Column 2* **Person by whom or on whose behalf the Direction must be signed**
A police force in England or Wales	The chief officer of police for that police force (within the meaning of the Police Act 1996**(b)**)

(a) Schedule 7 was inserted by S.I. 2000/1917.
(b) 1996 c.16.

A police force in Scotland	The chief constable of that police force (within the meaning of the Police (Scotland) Act 1997**(a)**)
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	(i) the Surgeon General, (ii) a Medical Director General, or (iii) a chief executive of an executive agency of the Ministry of Defence

".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
13th March 2003 Department of Health

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

D. C. Gowdy
Permanent Secretary,
11th March 2003 Department of Health, Social Services and Public Safety

(a) 1997 c.77.

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 descriptions 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 by or in accordance with the directions of such a practitioner.

Articles 2, 3, 5, 6, 8, 12, 13 and 16 make provision for nurses and pharmacists meeting certain conditions ("supplementary prescribers") to prescribe and administer prescription only medicines in accordance with clinical management plans relating to individual patients. Article 3 amends article 2 of the principal Order, so that supplementary prescribers are "appropriate practitioners" able to prescribe prescription only medicines. Article 5 amends article 3A of the principal Order, so that an extended formulary nurse prescriber may prescribe medicinal products without complying with the conditions in article 3A, if they are a supplementary prescriber complying with the new article 3B. Article 6 inserts new articles 3B and 3C into the principal Order: article 3B specifies the conditions as to the cases and circumstances in which supplementary prescribers may prescribe and administer prescription only medicines, including the requirement to prescribe in accordance with a clinical management plan; article 3C sets out when the conditions on administration by supplementary prescribers and extended formulary nurse prescribers do not apply. Article 16 inserts a new Schedule 3B into the principal Order, which sets out the requirements for clinical management plans. Articles 8, 12 and 13 make consequential amendments.

Articles 4 and 7 provide that certain medicinal products consisting of or containing aloxiprin, aspirin or paracetamol are prescription only medicines, unless the quantity sold or supplied is less than 100.

Article 9 provides that medicinal products are exempt from the restrictions on prescription only medicines, if they consist of or contain solely certain substances at high dilutions.

Articles 2, 10, 11 and 17 make provision for the supply or administration of prescription only medicines under a Patient Group Direction (i.e. a written direction providing for the supply or administration of a description or class of medicines to persons generally) to assist the provision of health care by certain non-NHS health care providers (i.e. a provider of health care other than a National Health Service body or a person providing services under an arrangement with such a body). In particular, Article 10 amends article 12C of the principal Order so as to enable a person conducting a retail pharmacy business to supply or administer prescription only medicines under an arrangement with certain non-NHS health care providers in accordance with a Patient Group Direction. Article 11 inserts new articles 12D and 12E into the principal Order—

(a) article 12D provides for the supply and administration of prescription only medicines by designated health professionals in the course of the business of an independent hospital, clinic or agency, or nursing home, in accordance with a Patient Group Direction; and

(b) article 12E provides for the supply and administration of prescription only medicines by designated health professionals in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces, in accordance with a Patient Group Direction.

Article 17 inserts new Part IIA of Schedule 7 to the principal Order, which specifies the persons by whom or on whose behalf a Patient Group Direction for the police, prison services or armed forces must be signed.

Articles 14 and 15 make a number of minor amendments to the lists of substances which may be prescribed by nurse prescribers, including the addition of water for injections and, in relation to extended formulary nurse prescribers, the deletion of inactivated polio vaccine and the addition of emedastine and mizolastine.

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.

STATUTORY INSTRUMENTS

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