
STATUTORY INSTRUMENTS

2000 No. 1917

MEDICINES

**The Prescription Only Medicines
(Human Use) Amendment Order 2000**

<i>Made</i>	- - - -	<i>17th July 2000</i>
<i>Laid before Parliament</i>		<i>19th July 2000</i>
<i>Coming into force</i>	- -	<i>9th August 2000</i>

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) and (5) 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 Safety of Medicines pursuant to sections 58(6) and 129(7) of that Act, and after 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 2000 and shall come into force on 9th August 2000.

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

Amendments of the principal Order with respect to sale and supply by hospitals and national health service bodies

2. The principal Order is amended as follows—

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- (1) 1968 c. 67; the expressions “the appropriate Ministers” and “the Health Ministers” are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388.
- (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 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, and 1999/3463.

- (a) in paragraph (2) of article 1 of the principal Order, there is inserted, at the appropriate place in the alphabetical order of the entries in that paragraph, the following entries—

““Common Services Agency” means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978(4);

“Community marketing authorization” means a marketing authorization granted by the European Community under Council Regulation (EEC) No. 2309/93(5);

“Health Authority”—

(a) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977(6);

(b) in relation to Scotland, means a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and

(c) in relation to Northern Ireland, means a Health and Social Services Board established under Article 16 of the Health and Personal Social Services (Northern Ireland) Order 1972(7);

“homoeopathic certificate of registration” means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994(8);

“marketing authorization” includes a reference both to a United Kingdom marketing authorization and to a Community marketing authorization;

“NHS trust”—

(a) in relation to England and Wales, has the same meaning as in the National Health Service and Community Care Act 1990(9);

(b) in relation to Scotland, has the same meaning as in the National Health Service (Scotland) Act 1978; and

(c) in relation to Northern Ireland, means a Health and Social Services trust established under article 10 of the Health and Social Services (Northern Ireland) Order 1991(10);

“Patient Group Direction” means—

(a) in connection with the supply of a prescription only medicine as referred to in article 12A(2), 12B or 12C, a written direction relating to the supply and administration of a description or class of prescription only medicine; or

(b) in connection with the administration of a prescription only medicine as referred to in article 12A(2), 12B or 12C, a written direction relating to the administration of a description or class of prescription only medicine,

and which, in the case of either (a) or (b)—

(i) is signed by a doctor or dentist, and by a pharmacist; and

(ii) relates to supply and administration, or to administration, to persons generally (subject to any exclusions which may be set out in the Direction);

(4) 1978 c. 29.

(5) OJ No. L214, 24.8.93, p.1.

(6) 1977 c. 49; section 8, which deals with the establishment of Health Authorities, was inserted by section 1 of the Health Authorities Act 1995 (c. 17).

(7) S.I. 1972/1265 (N.I. 14).

(8) S.I. 1994/105, amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566 and 2000/592.

(9) 1990 c. 19.

(10) S.I. 1991/194 (N.I. 1).

“Primary Care Trust” has the same meaning as in the National Health Service Act 1977(11);

“Special Health Authority”—

- (a) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977(12);
- (b) in relation to Scotland, means a Special Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and
- (c) in relation to Northern Ireland, means a Special Health and Social Services Agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990(13);

“state registered paramedic” means a person who is registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Paramedics Board(14);

“United Kingdom marketing authorization” means a marketing authorization granted by the licensing authority under the Medicines For Human Use (Marketing Authorisations Etc.) Regulations 1994 (including a product licence having effect as such an authorization by virtue of Schedule 6 to those Regulations)(15).”;

- (b) in article 1 of the principal Order, after paragraph (6), there is added—

“(7) In articles 12 to 12C, a reference to a prescription only medicine being sold or supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a particular person, or in accordance with a Patient Group Direction, includes a reference to it being sold or supplied in accordance with such directions or such a Direction.

(8) In articles 12A and 12C, a reference to an arrangement for the supply or administration of prescription only medicines includes a reference to an arrangement which covers such supply or administration and other matters.

(9) In Schedule 7, Part I, a reference to treatment of a clinical situation includes a reference to any form of management of that situation.”;

- (c) for article 12 of the principal Order, there is substituted—

“Exemption for sale or supply in hospitals

12. 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 the written directions of a doctor or dentist relating to that person notwithstanding that those directions do not satisfy the conditions specified in article 15(2).”;

- (d) after article 12 of the principal Order, there is inserted—

(11) Section 16A, which deals with the establishment of Primary Care Trusts, was inserted by section 2 of the Health Act 1999 (c. 8).

(12) See section 11 which was amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 2, and by the Health Act 1999 (c. 8), Schedule 4, paragraph 6.

(13) S.I. 1990/247 (N.I. 3).

(14) 1960 c. 66; section 2(1) of the Act has effect as if it mentioned the profession of paramedic, by virtue of S.I. 1999/1853.

(15) S.I. 1994/3144, amended by 1998/3105 and 2000/292.

“Exemptions for the supply and administration of prescription only medicines by national health service bodies

12A.—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the supply of a prescription only medicine by—

- (a) the Common Services Agency;
- (b) a Health Authority or Special Health Authority;
- (c) an NHS trust;
- (d) a Primary Care Trust; or
- (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply of prescription only medicines,

where the medicine is supplied for the purpose of being administered to a particular person in accordance with the written directions of a doctor or dentist relating to that person notwithstanding that those directions do not satisfy the conditions specified in article 15(2).

(2) 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 by—

- (a) the Common Services Agency;
- (b) a Health Authority or Special Health Authority;
- (c) an NHS trust;
- (d) a Primary Care Trust; or
- (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply or, as the case may be, the administration of prescription only medicines,

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 (3) are satisfied.

(3) 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 on behalf of the person specified in column 2 of the Table in Part II of Schedule 7 to this Order (“the authorising person”) against the entry in column 1 of that Table for the class of person by whom the medicine is supplied or administered;
- (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, 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

- (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.
- (4) In this article, “excepted person” means—
 - (a) a doctor or dentist; or
 - (b) a person lawfully conducting a retail pharmacy business within the meaning of section 69.

Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist doctors or dentists in providing national health services

12B.—(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 a doctor or dentist in the provision of, respectively, NHS primary medical services or NHS primary dental services;
 - (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 doctor or dentist in question in providing the services referred to in paragraph (1)(a) (whether or not it also relates to such supply or administration in order to assist any other doctor or dentist);
 - (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 the doctor or dentist in question or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
 - (ii) on behalf of the health authority—
 - (a) in the case of the provision of general medical services or general dental services, with which an arrangement has been made for the provision of those services; or
 - (b) in the case of the performance of personal medical services or personal dental services, which is a party to the pilot scheme under which those services are provided;
 - (e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply or, as the case may be, the administration of prescription

only medicines under the Patient Group Direction, by the doctor or dentist in question, or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; 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.
- (3) In this article—
- (a) a reference to the provision of NHS primary dental services shall be construed as a reference to—
- (i) in relation to England and Wales, the provision of general dental services under Part II of the National Health Service Act 1977, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997⁽¹⁶⁾;
 - (ii) in relation to Scotland, the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and
 - (iii) in relation to Northern Ireland, the provision of general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972⁽¹⁷⁾, or the performance of personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997⁽¹⁸⁾;
- (b) a reference to the provision of NHS primary medical services shall be construed as a reference to—
- (i) in relation to England and Wales, the provision of general medical services under Part II of the National Health Service Act 1977, or the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997;
 - (ii) in relation to Scotland, the provision of general medical services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and
 - (iii) in relation to Northern Ireland, the provision of general medical services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal medical services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997.

Exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction

12C.—(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 by a person lawfully conducting a retail pharmacy business within the meaning of section 69 where—

⁽¹⁶⁾ 1997 c. 46.

⁽¹⁷⁾ S.I. 1972/1265 (N.I. 14).

⁽¹⁸⁾ 1997/1177 (N.I. 7).

- (a) the medicine is supplied or, as the case may be, is administered by such a person pursuant to an arrangement made with the Common Services Agency, a Health Authority, a Special Health Authority, an NHS trust or a Primary Care Trust for the supply or, as the case may be, the administration of prescription only medicines;
 - (b) 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
 - (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 by the person lawfully conducting a retail pharmacy business who supplies or, as the case may be, administers the 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 on behalf of the body with which an arrangement has been made as referred to in paragraph (1)(a); and
 - (d) 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.”; and
- (e) after Schedule 6 to the principal Order, there is inserted—

“**SCHEDULE 7**

Articles 12A to 12C

PART I

**PARTICULARS TO BE INCLUDED
IN A PATIENT GROUP DIRECTION**

- (a) the period during which the Direction shall have effect;
- (b) the description or class of prescription only medicine to which the Direction relates;
- (c) whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;
- (d) the clinical situations which prescription only medicines of that description or class may be used to treat;
- (e) the clinical criteria under which a person shall be eligible for treatment;
- (f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;
- (g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;
- (h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;

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- (i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;
- (j) the applicable dosage or maximum dosage;
- (k) the route of administration;
- (l) the frequency of administration;
- (m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;
- (n) whether there are any relevant warnings to note, and, if so, what warnings;
- (o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- (p) arrangements for referral for medical advice;
- (q) details of the records to be kept of the supply, or the administration, of medicines under the Direction.

PART II

PERSONS ON WHOSE BEHALF A PATIENT GROUP DIRECTION MUST BE SIGNED

Column 1	Column 2
Class of person by whom a prescription only medicine is supplied or administered	Person on whose behalf the Direction must be signed
Common Services Agency	The Agency
Health Authority	The Health Authority
Special Health Authority	The Special Health Authority
NHS trust	The trust
Primary Care Trust	The Trust
A person who supplies or administers a prescription only medicine pursuant to an arrangement made with the Common Services Agency, a Health Authority, a Special Health Authority, an NHS trust or a Primary Care Trust	The Common Services Agency, where the arrangement has been made with the Agency; or the Health Authority, Special Health Authority, NHS trust or Primary Care Trust with which the arrangement has been made

PART III

CLASSES OF INDIVIDUAL BY WHOM SUPPLIES MAY BE MADE

Individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, or individuals who are state registered paramedics.

Pharmacists.

Registered health visitors(19).

Registered midwives.

Registered nurses.

Registered ophthalmic opticians.

State registered chiropodists.

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Orthoptists Board (state registered orthoptists)(20).

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Physiotherapists Board (state registered physiotherapists).

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Radiographers Board (state registered radiographers).”.

Amendment of Schedule 1 to the principal Order concerning specified substances and exemptions from the restrictions on sale and supply

3. In Schedule 1 to the principal Order (which specifies substances which, if included in medicinal products, make those products prescription only medicines, and exemptions from the restrictions on sale and supply of prescription only medicines)—

(a) in relation to the substance Ibuprofen, there are inserted the following entries—

in column 2—

“(3) 10.0 per cent”,

in column 3—

“(3) External”,

in column 4—

“(3) 125 mg (MD) 500 mg (MDD)”, and

in column 5—

“(3) Container or package containing not more than 100 g of medicinal product”;

(b) there is inserted in column 1, 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, against that entry there is inserted in columns 2, 3 and 5 the corresponding entries in columns 2, 3 and 5 below—

Column 1 Substance	Column 2 Maximum strength	Column 3 Use, pharmaceutical form or route of administration	Column 5 Maximum quantity
Terbinafine Hydrochloride	1.0 per cent	External use for the treatment of	Container or package containing not more than 15

(19) By virtue of section 7(7) of the Nurses, Midwives and Health Visitors Act 1997 (c. 24), “registered”, in relation to health visitors, means registered in the register maintained under that section by virtue of qualifications in health visiting.

(20) Section 2(1) of the Act has effect as if it mentioned the profession of orthoptist, by virtue of S.I. 1966/990.

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Column 1 Substance	Column 2 Maximum strength	Column 3 Use, pharmaceutical form or route of administration	Column 5 Maximum quantity
		tinea pedis and tinea cruris	g of medicinal product.

; and

(c) there is inserted in column 1, at the appropriate place in the alphabetical order of the entries as they appear in that column, each of the following substances—

“Acamprosate”

“Aceclofenac”

“Alendronate Sodium”

“Anastrozole”

“Didanosine”

“Eformoterol Fumarate”

“Imidapril Hydrochloride”

“Mirtazapine”

“Moxonidine”

“Omeprazole Magnesium”

“Ranitidine Bismuth Citrate”

“Rimexolone”

“Sertraline Hydrochloride”

“Sevoflurane”

“Tazarotene”

“Topiramate”.

Signed by authority of the Secretary of State for Health

15th July 2000

Hunt
Parliamentary Under Secretary of State,
Department of Health

17th July 2000

Bairbre de Brún
Minister of Health, Social Services and Public
Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 (the principal Order) by substituting a revised article 12, and inserting new articles 12A, 12B, 12C and Schedule 7. These amendments provide for the following new exemptions from the restrictions in section 58(2) of the Medicines Act 1968—

- (a) in article 12A, an exemption from section 58(2)(a) for the supply of a prescription only medicine by a specified national health service body, for administration in accordance with the patient specific directions of a doctor or dentist;
- (b) in article 12A, an exemption from section 58(2) for the supply or administration of a prescription only medicine by a specified national health service body, where the product is supplied for the purpose of being administered, or is administered, by a designated health professional in accordance with a Patient Group Direction (i.e. a written direction providing for the supply and administration, or administration, of a description or class of prescription only medicine to persons generally), where the Direction is signed by a doctor or a dentist and by a pharmacist, and certain other conditions are satisfied;
- (c) in article 12B, an exemption from section 58(2) for the supply or administration of a prescription only medicine by a designated health professional in order to assist a doctor or dentist in providing NHS services, where the product is supplied or administered in accordance with a Patient Group Direction, and the conditions referred to in (b) above are satisfied;
- (d) in article 12C, an exemption from section 58(2) for the supply or administration of a prescription only medicine by a person lawfully conducting a retail pharmacy business under an arrangement with a national health service body, where the product is supplied or administered in accordance with a Patient Group Direction and the conditions referred to in (b) above are satisfied.

The Order also amends Schedule 1 to the principal Order (which specifies substances which, if included in medicinal products, make them prescription only medicines, and exemptions from the restrictions in section 58(2) on sale and supply of prescription only medicines) and provides for—

- (i) an exemption from those restrictions for products containing the substance Ibuprofen where they are for external use, of maximum strength 10 per cent, have a maximum pack size of 100 grams, and are for administration at a maximum dose of 125mg and a maximum daily dose of 500mg;
- (ii) the inclusion in Schedule 1 of the substance Terbinafine Hydrochloride, with an exemption for products which are for external use for the treatment of tinea pedis or tinea cruris, with a maximum pack size of 15 grams and a maximum strength of 1 per cent; and
- (iii) the inclusion in Schedule 1 of the substances Acamprosate, Aceclofenac, Alendronate Sodium, Anastrozole, Didanosine, Eformoterol Fumarate, Imidapril Hydrochloride, Mirtazapine, Moxonidine, Omeprazole Magnesium, Ranitidine Bismuth Citrate, Rimexolone, Sertraline Hydrochloride, Sevoflurane, Tazarotene and Topiramate.

An assessment of the cost to business of complying with this Order has been made, copies of which have been placed in the libraries of both Houses of Parliament. Further 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.

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