STATUTORY INSTRUMENTS

1997 No. 1830

The Prescription Only Medicines (Human Use) Order 1997

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Order 1997 and shall come into force on 18th August 1997.

(2) In this Order, unless the context otherwise requires–

"the Act" means the Medicines Act 1968;

"aerosol" means a product which is dispersed from its container by a propellent gas or liquid;

"appropriate nurse practitioner" means–

(a) a person who–

(i) is registered in Part 1 or 12 of the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979(**1**) (referred to below in this definition as "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(**2**); 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;

"controlled drug" has the meaning assigned to it by section 2 of the Misuse of Drugs Act 1971(**3**);

"cyanogenetic substances" means preparations which–

(a) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17, or

(b) contain more than 0.1 per cent by weight of any substance having the formula either α-Cyanobenzyl-6-O-β-d-glucopyranosyl-β-d-glucopyranoside or α-Cyanobenzyl-β-d-glucopy ranosiduronic acid;

"dosage unit" means–

(a) where a medicinal product is in the form of a tablet or capsule or is an article in some other similar pharmaceutical form, that tablet, capsule or other article, or

(b) where a medicinal product is not in any such form, the unit of measurement which is used as the unit by reference to which the dose of the medicinal product is measured;

"external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read

(**1**) 1979 c. 36; the Parts of the professional register were determined by S.I. 1983/667, amended by S.I. 1989/104 and 1989/1455.
(**2**) Approved by S.I. 1983/873, to which there are amendments not relevant to this Order.
(**3**) 1971 c. 38.

accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

"health prescription" means a prescription issued by a doctor, dentist or nurse prescriber under or by virtue of–

(a) in England and Wales, the National Health Service Act 1977(**4**),

(b) in Scotland, the National Health Service (Scotland) Act 1978(**5**), and

(c) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(**6**);

"inhaler" does not include an aerosol;

"master" has the same meaning as in section 313(1) of the Merchant Shipping Act 1995(**7**);

"maximum daily dose" or "MDD" means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered in a period of 24 hours;

"maximum dose" or "MD" means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered at any one time;

"maximum strength" means–

(a) the maximum quantity of a substance by weight or volume contained in a dosage unit of a medicinal product;

(b) the maximum percentage of a substance contained in a medicinal product calculated in any of the following ways–

(i) weight in weight,

(ii) weight in volume,

(iii) volume in weight, or

(iv) volume in volume,

and if the maximum percentage calculated in those ways differs, the higher or highest such percentage;

"medicinal product" includes any article or substance in respect of which section 58 of the Act has effect by virtue of an order made under section 104 of the Act, but does not include–

(a) a medicinal product which is a veterinary drug as defined in section 132(1) of the Act or

(b) an article or substance in respect of which section 58 has such effect where that article or substance is only to be administered to animals;

"the Misuse of Drugs Regulations" means, in relation to England, Wales and Scotland, the Misuse of Drugs Regulations 1985(**8**) and in relation to Northern Ireland, the Misuse of Drugs (Northern Ireland) Regulations 1986(**9**);

"occupational health scheme" means a scheme in which a person, in the course of a business carried on by him, provides facilities for his employees for the treatment or prevention of disease;

(**4**) 1977 c. 49.
(**5**) 1978 c. 29.
(**6**) S.I. 1972/1265 (N.I. 14).
(**7**) 1995 c. 21.
(**8**) S.I. 1985/2066.
(**9**) SR 1986 No. 52.

"offshore installation" means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(**10**) which is within–

(a) tidal waters and parts of the sea in or adjacent to the United Kingdom up to the seaward limits of territorial waters;

(b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(**11**);

"operator", in relation to an aircraft, means the person for the time being having the management of the aircraft;

"parenteral administration" means administration by breach of the skin or mucous membrane;

"prescription only medicine" means a medicinal product of a description or falling within a class specified in article 3 of this Order;

"prolonged release" in relation to a medicinal product means a formulation of that product which–

(a) is used to reduce the rate at which the active ingredient in that product is released after administration, and

(b) is sold or supplied as a prolonged, controlled or sustained release medicinal product;

"registered midwife" means a person who is registered in Part 10 of the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979;

"registered nurse" means a person who is registered in the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979;

"registered ophthalmic optician" means a person who is registered in either of the Registers of ophthalmic opticians maintained under section 7(a) of the Opticians Act 1989(**12**);

"repeatable prescription" means a prescription which contains a direction that it may be dispensed more than once;

"sell" means sell by retail as defined in section 131 of the Act and "sale" has a corresponding meaning;

"soap" means any compound of a fatty acid with an alkali or amine;

"state registered chiropodist" means a person who is registered in the Register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960(**13**) by the Chiropodists Board;

"supply" means supply in circumstances corresponding to retail sale as defined in section 131 of the Act;

"unit preparation" means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert diluent, and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances.

(3) For the purposes of this Order, the equivalence of a substance to a reference material shall be determined by calculating the amount of that reference material which is contained in that substance either by weight or, where the amount of the reference material is specified in terms of international units of activity, those units.

(4) In this Order, unless the context otherwise requires, a reference–

(**10**) 1971 c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).
(**11**) 1964 c. 29.
(**12**) 1989 c. 44.
(**13**) 1960 c. 66.

(a) to a numbered section is to the section of the Act which bears that number,

(b) to a numbered article or Schedule is to the article of, or Schedule to, this Order which bears that number,

(c) in an article or in a Part of a Schedule to a numbered paragraph is to the paragraph of that article or Part of that Schedule which bears that number, and

(d) in a paragraph to a lettered sub-paragraph is to the sub-paragraph of that paragraph which bears that letter.

(5) In Schedules 1 to 3–

(a) entries specified in columns 2 to 5 relate to the substances listed in column 1 against which they appear and where, in relation to a particular substance listed in column 1, an entry in columns 2 to 5 bears a number or letter it relates only to such entries in the other of those columns as bear the same number or letter;

(b) the following abbreviations are used:

"g" for gram,

"iu" for international unit of activity,

"mcg" for microgram,

"mg" for milligram,

"ml" for millilitre.

(6) In Schedule 3, the abbreviation "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.

Appropriate practitioners

2. For the purposes of section 58 (medicinal products on prescription only), the following shall be appropriate practitioners–

(a) in relation to the descriptions and classes of medicinal products specified in article 3, doctors, dentists, veterinary surgeons and veterinary practitioners;

(b) in relation to the descriptions and classes of medicinal products specified in Schedule 3, appropriate nurse practitioners.

Medicinal products on prescription only

3. Subject to article 6, the following descriptions and classes of medicinal products are specified for the purposes of section 58, namely–

(a) medicinal products consisting of or containing a substance listed in column 1 of Schedule 1;

(b) medicinal products that are controlled drugs;

(c) medicinal products that are for parenteral administration, other than preparations of insulin for parenteral administration;

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

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

(f) medicinal products for human use which are classified as subject to medical prescription in marketing authorizations granted under Council Regulation 2309/93(**14**);

(**14**) OJ No. L214, 24.8.93, p. 1.

(g) medicinal products–

(i) which are not of a description and do not fall within a class specified in subparagraphs (a) to (f),

(ii) which are of a description in respect of which the conditions specified in section 59(1) are satisfied, and

(iii) in respect of which a product licence or marketing authorization has been granted which contains a provision to the effect that the method of sale or supply of the medicinal product is to be only in accordance with a prescription given by an appropriate practitioner.

Duration of special provisions in relation to new medicinal products

4. The duration specified for the purposes of section 59(2)(a) (duration of restrictions for certain new products) shall be a period of 5 years.

Exempt medicinal products

5.—(1) A medicinal product shall be exempt from the restrictions imposed by section 58(2)(a) (restrictions on sale or supply) if it, or a substance in it, is listed in column 1 of Schedule 1 and there–

(a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or

(b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.

(2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.

(3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.

(4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use–

(a) where a purpose for which it may be used is so specified, for that purpose;

(b) where the class of persons in whom it may be used is so specified, in persons of that class.

(5) Where a pharmaceutical form is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied in that pharmaceutical form.

(6) Where a maximum dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum dose which does not exceed that specified maximum dose.

(7) Subject to paragraph (8), where a maximum daily dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum daily dose which does not exceed that specified maximum daily dose.

(8) A medicinal product which contains more than one of the substances–

Atropine

Atropine Methobromide

Atropine Methonitrate

Atropine Oxide Hydrochloride

Atropine Sulphate

Hyoscine

Hyoscine Butylbromide

Hyoscine Hydrobromide

Hyoscine Methobromide

Hyoscine Methonitrate

Hyoscyamine

Hyoscyamine Hydrobromide

Hyoscyamine Sulphate,

satisfies the condition only where it is sold or supplied for use at a maximum daily dose which does not exceed 1 milligram in total of the alkaloids derived from belladonna, hyoscyamus, stramonium or other solanaceous plant which are contained in that medicinal product.

(9) Where a maximum period of use or a maximum frequency of use is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use for a maximum period or frequency, as the case may be, which does not exceed the maximum period of use or the maximum frequency of use which is so specified.

(10) Where a maximum quantity is specified in column 5 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it, or where so specified in that column, the medicinal product which contains that substance is sold or supplied in a quantity which does not exceed that specified maximum quantity.

(11) In paragraphs (2) to (7) and (9) and (10) a reference to a numbered column is a reference to the column bearing that number in Schedule 1.

Circumstances in which controlled drugs and medicinal products authorized by the European Community are not prescription only medicines

6.—(1) A medicinal product shall not be a prescription only medicine by reason that it is a controlled drug listed in Schedule 2 to the Misuse of Drugs Act 1971 where, it–

(a) contains not more than one of the substances listed in column 1 of Schedule 2 to this Order and no other controlled drug;

(b) contains that substance at a strength that does not exceed the maximum strength specified in column 2 of that Schedule; and

(c) is sold or supplied–

(i) in such pharmaceutical form as may be specified in column 3 of that Schedule, and

(ii) for use at a maximum dose which does not exceed that specified in column 4 of that Schedule.

(2) A medicinal product for human use in respect of which a marketing authorization has been granted under Council Regulation 2309/93/EEC(**15**) shall not be a prescription only medicine where that authorization does not classify the medicinal product as subject to medical prescription.

Exemption for parenteral administration in an emergency to human beings of certain prescription only medicines

7. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of any of the following medicinal products for parenteral administration–

Adrenaline Injection 1 in 1000 (1 mg in 1 ml)

Atropine Sulphate Injection

Chlorpheniramine Injection

Cobalt Edetate Injection

Dextrose Injection Strong B.P.C.

Diphenhydramine Injection

Glucagon Injection

Hydrocortisone Injection

Mepyramine Injection

Promethazine Hydrochloride Injection

Snake Venom Antiserum

Sodium Nitrite Injection

Sodium Thiosulphate Injection

Sterile Pralidoxime

where the administration is for the purpose of saving life in an emergency.

Exemptions for emergency sale or supply

8.—(1) The restrictions imposed by section 58(2)(a) (restriction on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to in paragraph (1) are–

(a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor who by reason of an emergency is unable to furnish a prescription immediately;

(b) that the doctor has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours of the sale or supply;

(c) that the prescription only medicine is sold or supplied in accordance with the directions of the doctor requesting it;

(d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;

(e) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**16**) within the time specified in

(**15**) OJ No. L214, 24.8.93, p. 1.
(**16**) S.I. 1980/1923, amended by S.I. 1997/1831.

that regulation stating the particulars required under paragraph 1 of Schedule 2 to those Regulations.

(3) The restrictions imposed by section 58(2)(a) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (4) are satisfied.

(4) The conditions referred to in paragraph (3) are–

(a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting a prescription only medicine and has satisfied himself–

(i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay,

(ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor for the person requesting it, and

(iii) as to the dose which in the circumstances it would be appropriate for that person to take;

(b) that no greater quantity of the prescription only medicine than will provide 5 days' treatment is sold or supplied except that where the prescription only medicine–

(i) is an aerosol for the relief of asthma, an ointment or cream, and has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply may be sold or supplied,

(ii) is an oral contraceptive, a quantity sufficient for a full treatment cycle may be sold or supplied,

(iii) is an antibiotic for oral administration in liquid form, the smallest quantity that will provide a full course of treatment may be sold or supplied;

(c) subject to paragraph (5), that the prescription only medicine does not consist of or contain a substance specified in Schedule 4 to this Order and is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;

(d) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within the time specified in that regulation stating the particulars required under paragraph 3 of Schedule 2 to those Regulations;

(e) that the container or package of the prescription only medicine is labelled so as to show–

(i) the date on which the prescription only medicine is sold or supplied,

(ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,

(iii) the name of the person requesting the prescription only medicine,

(iv) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied, and

(v) the words “Emergency Supply”.

(5) The conditions specified in paragraphs (2)(d) and (4)(c) shall not apply where the prescription only medicine consists of or contains phenobarbitone or phenobarbitone sodium (but no other substance specified in Schedule 4 to this Order or Schedule 1, 2 or 3 to the Misuse of Drugs Regulations) and is sold or supplied for use in the treatment of epilepsy.

Exemption for non-parenteral administration to human beings

9. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of a prescription only medicine which is not for parenteral administration.

Exemption for medicinal products at high dilutions

10. 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, any of the substances listed in column 1 of Schedule 1 or 2, only one or more unit preparation of such substances, if–

(a) each such unit preparation has been diluted to at least one part in a million (6x), and the person selling, supplying or administering the medicinal product has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required; or

(b) each such unit preparation has been diluted to at least one part in a million million (6c).

Exemptions for certain persons

11.—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply–

(a) to the sale or supply by a person listed in column 1 of Part I of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied;

(b) to the supply by a person listed in column 1 of Part II of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

(2) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration by a person listed in column 1 of Part III of Schedule 5 of the prescription only medicines for parenteral administration listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

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 any prescription only medicine in the course of the business of a hospital where the prescription only medicine is sold or supplied in accordance with the written directions of a doctor or dentist notwithstanding that those directions do not satisfy the conditions specified in article 15(2).

Exemption in cases involving another's default

13. 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 person who, having exercised all due diligence, believes on reasonable grounds that the product sold or supplied is not a prescription only medicine.

Exemption in the case of a forged prescription

14. 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

forged prescription where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.

Prescriptions

15.—(1) For the purposes of section 58(2)(a) a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.

(2) The conditions referred to in paragraph (1) are that the prescription–

(a) shall be signed in ink with his own name by the appropriate practitioner giving it;

(b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, in which case it may be written by means of carbon paper or similar material;

(c) shall contain the following particulars–

(i) the address of the appropriate practitioner giving it,

(ii) the appropriate date,

(iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, an appropriate nurse practitioner, a veterinary surgeon or a veterinary practitioner,

(iv) where the appropriate practitioner giving it is a doctor, dentist or appropriate nurse practitioner, the name, address and the age, if under 12, of the person for whose treatment it is given, and

(v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;

(d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;

(e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.

(3) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to a sale or supply of a prescription only medicine which is not in accordance with a prescription given by an appropriate practitioner by reason only that a condition specified in paragraph (2) is not satisfied where the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that that condition is satisfied in relation to that sale or supply.

(4) In paragraph (2) "the appropriate date" means–

(a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and

(b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it;

and, for the purposes of sub-paragraphs (d) and (e) of that paragraph, where a health prescription bears both the date on which it was signed and a date indicated as being that before which it shall not be dispensed, the appropriate date is the later of those dates.

Revocations

16.—(1) The Orders specified in Schedule 6 are revoked.

(2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(**17**) articles 2 to 6 and Schedules 1 and 2 are revoked.

Signed by authority of the Secretary of State for Health

Baroness Jay
Minister of State,
21st July 1997 Department of Health

Win Griffiths
Parliamentary Under Secretary of State, Welsh
25th July 1997 Office

Sam Galbraith
Parliamentary Under Secretary of State, The
23rd July 1997 Scottish Office

Jeff Rooker
Minister of State, Ministry of Agriculture,
25th July 1997 Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 22nd July 1997.

D. C. Gowdy
Permanent Secretary

(**17**) S.I. 1989/1852.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th July 1997.

P. Small
Permanent Secretary