STATUTORY INSTRUMENTS

1977 No. 2132

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1977

Made - - - -	*20th December* 1977
Laid before Parliament	*5th January* 1978
Coming into Operation	*1st February* 1978

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 61, 66(1) and 67(6) of the Medicines Act 1968(**a**) and now vested in them(**b**) and the said Secretary of State concerned with health in England and in Wales and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of powers conferred by section 108(4) and (7) of that Act and now vested in them(**c**) and the said Secretary of State concerned with health and with agriculture in Scotland in exercise of powers conferred by section 108(7) (as having effect in relation to Scotland by virtue of section 109(2) of that Act) and section 109(3) of that Act 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 the following regulations, and after taking into account the advice of the Medicines Commission, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1977 and shall come into operation on 1st February 1978.

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388 (1969 I, p. 1070)), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and section 1(3) of, and paragraph 2(1)(*b*) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**c**) In the case of the Secretary of State concerned with health in England and in Wales by virtue of Article 2 of the Secretary of State for Social Services Order 1968 (S.I. 1968/1699 (1968 III, p. 4585)).

(2) In these regulations—

(*a*) other than in sub-paragraph (*b*) of regulation 5(1) of these regulations, any reference to selling anything by way of wholesale dealing shall include any such sale by the person who manufactured it; and

(*b*) unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

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

"health prescription" means a prescription issued by a doctor or dentist under or by virtue of—

(i) in England and Wales, either the National Health Service Act 1946(**b**) and the National Health Service Reorganisation Act 1973(**c**) or the National Health Service Act 1977(**d**),

(ii) in Scotland, the National Health Service (Scotland) Acts 1947 to 1976, and

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

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

"pharmacy medicine" means any medicinal product which is not a prescription only medicine or a medicinal product on a general sale list;

"prescription only medicine" means a medicinal product of a description or falling within a class specified in Article 3 of the Medicines (Prescription Only) Order 1977(**f**);

"register" means a bound book and does not include any form of loose leaf register or card index;

"registered ophthalmic optician" means a person who is registered in either of the registers of ophthalmic opticians established and maintained under section 2(*a*) of the Opticians Act 1958(**g**);

"repeat prescription" means a prescription which contains a direction that it may be dispensed a stated number of times;

"state registered physiotherapist" means a person who is registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960(**h**) by the Physiotherapists Board;

"unit preparation" means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being further diluted tenfold, or serially in multiple powers of ten, in an inert diluent, and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances for the purposes of being administered to human beings;

(**a**) 1971 c. 38.
(**b**) 1946 c. 81.
(**c**) 1973 c. 32.
(**d**) 1977 c. 49.
(**e**) S.I. 1972/1265 (N.I. 14).
(**f**) S.I. 1977/2127.(1977 III, p. 5820).
(**g**) 1958 c. 32.
(**h**) 1960 c. 66.

and other expressions have the same meanings as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any enactment, order or regulations shall be construed as a reference to that enactment or order or to those regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order or regulations.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(a) shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Enforcement of sections 53, 54 *and* 66 *of the Act*

2.—(1) The food and drugs authority for each area in England and in Wales in respect of which there is a food and drugs authority and a local authority as defined by section 26(4) of the Food and Drugs (Scotland) Act 1956(b) in respect of their area in Scotland shall have power and be under a duty concurrently with the appropriate Minister within the meaning of section 108(11) of the Act as respects England and Wales and the Secretary of State as respects Scotland to enforce in England and in Wales or in Scotland as the case may be the provisions of sections 53, 54 and 66 of the Act in their application to premises which are not registered pharmacies other than those premises on which medicinal products specified in Articles 3 and 4 of the Medicines (Exemptions from Restrictions on the Retail Sale of Veterinary Drugs) Order 1977(c) are sold or supplied.

(2) The Pharmaceutical Society shall have power and be under a duty concurrently with the said appropriate Minister and the Secretary of State to enforce in England and in Wales or in Scotland as the case may be the provisions of sections 53, 54 and 66 of the Act in their application—

(*a*) to premises which are registered pharmacies, and

(*b*) to premises on which medicinal products specified in Articles 3 and 4 of the Medicines (Exemptions from Restrictions on the Retail Sale of Veterinary Drugs) Order 1977 are sold or supplied.

Safekeeping of certain veterinary drugs

3.—(1) For the purpose of the safekeeping of veterinary drugs to which this regulation applies, any person having or keeping the said veterinary drugs on premises at or from which veterinary drugs are sold by retail or supplied in circumstances corresponding to retail sale shall—

(*a*) store the said veterinary drugs in a part of the premises which is partitioned off or otherwise separated from the remainder of the premises and to which the public are not permitted access, and

(*b*) comply with any storage instructions appearing on the labels on containers or packages of or in leaflets supplied with the said veterinary drugs relating to refrigeration or other measures necessary for the safekeeping of the said veterinary drugs.

(a) 1889 c. 63.
(b) 1956 c. 30.
(c) S.I. 1977/2167. (1977 III, p. 6141).

(2) This regulation applies to veterinary drugs in respect of which an exemption from the restrictions imposed by section 52 of the Act applies by virtue of Article 3(1) or Article 4(1) of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977.

Location of automatic machines

4. Every automatic machine which is for use for the sale of any medicinal product in the automatic machines section of a general sale list shall be located in premises which the occupier of the premises in question is able to close so as to exclude the public.

Restrictions on persons to be supplied with certain medicinal products

5.—(1) Subject to the exceptions specified in paragraph (2) of this regulation, no person—

(*a*) being the holder of a product licence, or

(*b*) in the course of a business carried on by him and consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing,

shall sell a prescription only medicine by way of wholesale dealing to any person who does not fall within a class specified in Schedule 1 to these regulations.

(2) Notwithstanding the restrictions imposed by paragraph (1) above, the persons referred to in sub-paragraphs (*a*) and (*b*) of the said paragraph (1) may sell by way of wholesale dealing—

(*a*) to any person specified in column 1 of Schedule 4 to the Medicines (Prescription Only) Order 1977, prescription only medicines specified in relation to that person in column 2 of the said Schedule;

(*b*) to any person who sells by retail or supplies in circumstances corresponding to retail sale or administers medicinal products having 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, prescription only medicines which contain one or more unit preparations of any substance listed in column 1 of Parts I and II of Schedule 1 to the Medicines (Prescription Only) Order 1977 where the unit preparation has been diluted to at least one part in a million (6x);

(*c*) to a registered ophthalmic optician, eye ointment containing Oxyphenbutazone and prescription only medicines containing any of the following substances—

Amethocaine
Amethocaine hydrochloride
Butacaine sulphate
Lignocaine hydrochloride
Oxybuprocaine hydrochloride
Phenacaine
Proxymetacaine hydrochloride
Thymoxamine hydrochloride;

(*d*) to a state registered physiotherapist, Ethylmorphine hydrochloride solution or gel.

(3) Subject to the exceptions specified in paragraph (4) of this regulation, no person referred to in sub-paragraphs (*a*) and (*b*) of paragraph (1) of this regulation shall sell a pharmacy medicine by way of wholesale dealing to any person who does not fall within a class specified in Schedule 1 to these regulations.

(4) Notwithstanding the restrictions imposed by paragraph (3) above, the persons referred to in sub-paragraphs (*a*) and (*b*) of the said paragraph (1) may sell by way of wholesale dealing—

(*a*) to any person who requires pharmacy medicines for the purpose of administering them to human beings in the course of a business carried on by him, pharmacy medicines which are for the purpose of being so administered;

(*b*) to any person who, by virtue of an exemption from the restrictions imposed by section 52 of the Act conferred either by section 56 of the Act or by an order made under section 55(2)(*b*) or section 57(1) of the Act, is enabled to sell by retail or supply in circumstances corresponding to retail sale pharmacy medicines specified in the said exemptions other than by or under the supervision of a pharmacist, those pharmacy medicines specified in the said exemptions.

Pharmacy records

6.—(1) Subject to the following provisions of these regulations, every person lawfully conducting a retail pharmacy business shall—

(*a*) make or cause to be made an entry in respect of every sale or supply of a prescription only medicine (other than a sale or supply in pursuance of a health prescription or a prescription for oral contraceptives) in a register kept for that purpose, stating the particulars specified in paragraphs 2, 3 or 4 of Schedule 2 to these regulations as appropriate, and

(*b*) make or cause to be made the entries referred to in (*a*) above on the day the sale or supply takes place or, if that is not reasonably practicable, on the day next following that day.

(2) The requirements imposed by paragraph (1) of this regulation shall not apply in the following cases—

(*a*) where a separate record of such sale or supply is made in accordance with regulation 19 of the Misuse of Drugs Regulations 1973(**a**) or regulation 19 of the Misuse of Drugs (Northern Ireland) Regulations 1974(**b**),

(*b*) where a sale of a prescription only medicine is a sale by way of wholesale dealing if and so long as a copy of the order or invoice relating thereto is retained by the person lawfully conducting the retail pharmacy business who makes the sale.

(3) Every person lawfully conducting a retail pharmacy business shall preserve for a period of two years from the relevant date—

(*a*) the register kept under paragraph (1) of this regulation;

(**a**) S.I. 1973/797 (1973 I, p. 2549).
(**b**) S.R. of N.I. 1974 No. 272.

(*b*) prescriptions in accordance with which any prescription only medicine has been sold or supplied other than health prescriptions;

(*c*) orders or invoices referred to in paragraph (2)(*b*) of this regulation; and

(*d*) orders referred to in column 3 of Schedule 3 to the Medicines (Prescription Only) Order 1977 (conditions for certain exemptions from the restrictions imposed by section 58 of the Act).

(4) In paragraph (3) of this regulation "relevant date" means—

(*a*) in relation to sub-paragraph (*a*), the date on which the last entry was made in the register, and

(*b*) in relation to sub-paragraphs (*b*), (*c*) and (*d*), the date on which the prescription only medicine was sold or supplied except that where the prescription only medicine was sold or supplied in accordance with a repeat prescription the relevant date means the date on which the prescription was dispensed for the last time.

Record keeping in respect of certain veterinary drugs

7.—(1) Every person to whom the restrictions imposed by section 52 of the Act do not apply by virtue of Article 3(1) or Article 4(1) of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, shall make a record of every sale of a veterinary drug listed in Schedules 1, 2 and 3 of the said order stating the particulars specified in paragraph (3) of this regulation.

(2) The requirement imposed by paragraph (1) of this regulation shall not apply if there has been issued or received an invoice or an order containing the particulars specified in paragraph (3) of this regulation.

(3) The particulars referred to in the preceding paragraphs of this regulation are—

(*a*) the date the veterinary drug was sold,

(*b*) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the veterinary drug sold,

(*c*) the name and address of the person to whom the veterinary drug was sold.

(4) The persons referred to in paragraph (1) of this regulation shall keep the records referred to in the said paragraph (1) and the invoices and orders referred to in paragraph (2) of this regulation for a period of two years from the date of sale.

Offences

8. Any person who contravenes regulations 3, 4, 6 or 7 of these regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £400.

David Ennals,
Secretary of State for Social Services.

15th December 1977.

John Morris,
Secretary of State for Wales.

15th December 1977.

Bruce Millan,
Secretary of State for Scotland.

15th December 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 15th December 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 19th day of December 1977.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 20th day of December 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

SCHEDULE 1 Regulation 5(1) and (3)

CLASSES OF PERSONS FOR THE PURPOSES OF REGULATION 5 OF THESE REGULATIONS

Practitioners.

Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Act.

Authorities or persons carrying on the business of a hospital or health centre.

Holders of wholesale dealer's licences or persons to whom the restrictions imposed by section 8(3) of the Act (wholesale dealer's licences) do not apply by virtue of an exemption conferred by or under the Act.

Ministers of the Crown and Government departments and officers thereof.

Regulation 6(1)

SCHEDULE 2

PARTICULARS IN PHARMACY RECORDS

1. In this Schedule "the Prescription Only Order" means the Medicines (Prescription Only) Order 1977(a).

2. Where the sale or supply of a prescription only medicine is either in pursuance of a prescription given by a practitioner or is a sale or supply to which the provisions of Article 6(1) of the Prescription Only Order apply (emergency supply), the particulars referred to in regulation 6(1)(*a*) of these regulations are—

(a) the date on which the prescription only medicine was sold or supplied,

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

(c) the name and address of the practitioner giving it,

(d) the name and address of the person for whom or for whose animal, as the case may be, the prescription only medicine was prescribed,

(e) subject to (f) below, the date on the prescription, and

(f) in relation to the sale or supply of a prescription only medicine to which the provisions of the said Article 6(1) apply, when the prescription relating to such sale or supply is received, the date on which it is received.

3. Where the sale or supply of a prescription only medicine is a sale or supply to which the provisions of Article 6(3) of the Prescription Only Order apply (emergency supply), the particulars referred to in regulation 6(1)(*a*) of these regulations are—

(a) the date on which the prescription only medicine was sold or supplied,

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

(c) the name and address of the person requiring the prescription only medicine, and

(d) the nature of the emergency.

4. Where the sale or supply of a prescription only medicine is by way of wholesale dealing and no order or invoice relating thereto has been retained under regulation 6(2)(*b*) of these regulations or the sale or supply is otherwise in circumstances in which the restrictions imposed by section 58(2) of the Act do not apply, the particulars referred to in regulation 6(1)(*a*) of these regulations are—

(a) the date on which the prescription only medicine was sold or supplied,

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

(c) the name and address, trade, business or profession of the person to whom the prescription only medicine is sold or supplied,

(d) the purpose for which the prescription only medicine is sold or supplied.

(a) S.I. 1977/2127. (1977 III, p. 5820).

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations prescribe requirements relating to the safekeeping of certain veterinary drugs, the location of automatic machines for the sale of medicinal products and the keeping of records by persons lawfully conducting a retail pharmacy business and certain sellers of veterinary drugs. They also provide restrictions on the classes of persons who may be supplied with prescription only medicines and pharmacy medicines and provide exemptions from those restrictions.

The Regulations make provision for the enforcement by local authorities and the Pharmaceutical Society of sections 53 and 54 of the Medicines Act 1968 (sale of medicinal products on a general sale list and sale of medicinal products from automatic machines) and for the enforcement of regulations made under section 66 of that Act relating to dealings with medicinal products.

Regulation 8 makes it an offence to contravene regulations 3, 4, 6 or 7 of these regulations. Any person who contravenes regulation 5 shall be guilty of an offence under section 67(2) of the Medicines Act 1968.

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