STATUTORY INSTRUMENTS

1980 No. 1923

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980

Made - - - -	*8th December* 1980
Laid before Parliament	*23rd December* 1980
Coming into Operation	*30th January* 1981

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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 53(4), 61, 66(1), 67(6) and 129(1) of the Medicines Act 1968 (**a**) and now vested in them (**b**) and the 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 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 1980 and shall come into operation on 30th January 1981.

(**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), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No.1) Order 1978 (S.I. 1978/272) 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).

(2) In these regulations, unless the context otherwise requires,—

(*a*) "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**);

"effervescent", in relation to a tablet, means containing not less than 75 per cent, by weight of the tablet, of ingredients included wholly or mainly for the purpose of releasing carbon dioxide when the tablet is dissolved or dispersed in water;

"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) Act 1978(**e**), and

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

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

"pharmacy medicine" means a medicinal product which is not a prescription only medicine and which either—

(i) is not a medicinal product on a general sale list, or

(ii) is a product referred to in regulation 8 and is not presented for sale in the manner described in relation to that product in that regulation;

"prescription only medicine" means a medicinal product of a description or falling within a class specified in Article 3 of the Prescription Only Order;

"the Prescription Only Order" means the Medicines (Prescription Only) Order 1980(**g**);

"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(**h**);

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

"the Veterinary Drugs Exemption Order" means the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1979 (**i**);

(*b*) a reference to selling anything by way of wholesale dealing is to selling it to a person as being a person who buys it for one or more of the

(**a**) 1971 c.38.
(**b**) 1946 c.81.
(**c**) 1973 c.32.
(**d**) 1977 c.49.
(**e**) 1978 c.29.
(**f**) S.I.1972/1265 (N.I. 14).
(**g**) S.I. 1980/1921.
(**h**) 1958 c.32.
(**i**) S.I. 1979/45; relevant amending instruments are S.I. 1980/283, 1650.

purposes specified in section 131(2), except that in sub-paragraph (*b*) of regulation 5 (1) it does not include any such sale by the person who manufactured it, and a reference to supplying anything by way of wholesale dealing is to supplying it to a person as being a person who receives it for one or more of those purposes; and

(*c*) a reference to a numbered section is to the section of the Act which bears that number, a reference to a numbered regulation or Schedule is to the regulation in or Schedule to these regulations which bears that number and a reference in a regulation or Schedule to a numbered paragraph is to the paragraph which bears that number in that regulation or Schedule.

Enforcement of sections 53, 54 and 66

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 shall, in respect of their area, continue to have power and be under a duty concurrently with the appropriate Minister within the meaning of section 108(11) to enforce the provisions of sections 53 and 54 and regulations made under section 66 in the application of each of those provisions to premises which are neither registered pharmacies nor premises on which there are sold or supplied medicinal products specified in Articles 3 and 4 of the Veterinary Drugs Exemption Order.

(2) In Scotland, a local authority as defined by section 26(4) of the Food and Drugs (Scotland) Act 1956(**a**) shall, in respect of their area, continue to have power and be under a duty concurrently with the Secretary of State to enforce the provisions of sections 53 and 54 and regulations made under section 66 in the application of each of those provisions to premises which are neither registered pharmacies nor premises on which there are sold or supplied medicinal products specified in Articles 3 and 4 of the Veterinary Drugs Exemption Order.

(3) The Pharmaceutical Society shall continue to have power and be under a duty concurrently with the appropriate Minister within the meaning of section 108(11) in respect of England and Wales and with the Secretary of State in respect of Scotland to enforce in England, in Wales and in Scotland the provisions of sections 53 and 54 and regulations made under section 66 in the application of each of those provisions—

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

(*b*) to premises on which there are sold or supplied medicinal products specified in Articles 3 and 4 of the Veterinary Drugs Exemption Order.

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 those 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 those 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

(**a**) 1956 c.30.

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

(2) This regulation applies to veterinary drugs in respect of which there applies an exemption from the restrictions imposed by section 52 by virtue of Article 3(1) or Article 4(1) of the Veterinary Drugs Exemption Order.

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 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), 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 or a pharmacy medicine by way of wholesale dealing to any person who does not fall within a class specified in Schedule 1.

(2) Notwithstanding the restriction imposed by paragraph (1), there may be sold by way of wholesale dealing—

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

(*b*) to any person, such prescription only medicines referred to in Article 8 of the Prescription Only Order (certain products at dilutions of at least one part in a million) as that person may, by virtue of that Article, sell by retail or supply in circumstances corresponding to retail sale or administer free from the restrictions imposed by section 58;

(*c*) to a registered ophthalmic optician, eye ointment containing Oxyphenbutazone and prescription only medicines which are prescription only medicines by reason only that they contain any one or more of the following substances—

Amethocaine hydrochloride
Framycetin sulphate
Lignocaine hydrochloride
Oxybuprocaine hydrochloride
Proxymetacaine hydrochloride
Thymoxamine hydrochloride;

(*d*) to persons in relation to whom the restriction imposed by section 58(2)(*b*) (restriction on administration) does not apply by virtue of Article 12 of the Prescription Only Order, prescription only medicines for parenteral administration that are for the purpose of being administered to human beings in the circumstances specified in paragraph (2) of that Article;

(*e*) 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;

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

Pharmacy records

6.—(1) Subject to paragraph (2), every person lawfully conducting a retail pharmacy business shall—

(*a*) in respect of every sale or supply of a prescription only medicine, make or cause to be made an entry in a register kept for that purpose, stating the particulars specified in paragraphs 1,2,3 or 4 of Schedule 2 as appropriate, and

(*b*) make or cause to be made every such entry on the day the sale or supply takes place, or if that is not reasonably practicable, on the day next following that day, except that where the sale or supply is under Article 6(1) of the Prescription Only Order (emergency supply on doctor's undertaking to furnish prescription) the particulars specified in paragraph 1(*e*) and (*f*) of Schedule 2 may be entered on the day that the prescription relating to that sale or supply is received.

(2) The requirements imposed by paragraph (1) shall not apply where—

(*a*) the sale or supply is in pursuance of a health prescription or a prescription for oral contraceptives, or

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

(*c*) the sale is by way of wholesale dealing and the order or invoice relating to the sale or a copy thereof is retained by the person lawfully conducting the retail pharmacy business who makes the sale, or

(*d*) the sale or supply is to a person employed or engaged in connection with a scheme for testing the quality and checking the amount of drugs and appliances supplied under the National Health Service Act 1977, the National Health Service (Scotland) Act 1978 or the Health and Personal Social Services (Northern Ireland) Order 1972 or under any subordinate legislation made under those Acts or that Order, or

(*e*) in Scotland, the sale or supply is to a doctor and is in compliance with the arrangements referred to in paragraph 15(3) of Part I of Schedule 1 to the National Health Service (General Medical and Phar-

(**a**) The relevant orders are the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 (S.I.1977/2130), the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1979 (S.I. 1979/45, amended by S.I. 1980/283, 1650) and the Medicines (Pharmacy and General Sale-Exemption) Order 1980 (S.I. 1980/1924).

(**b**) S. I. 1973/797, to which there are no amendments relevant to the subject matter of these regulations.

(**c**) S. R. of N. I. 1974 No. 272, to which there are no amendments relevant to the subject matter of these regulations.

maceutical Services) (Scotland) Regulations 1974(**a**) (arrangements under which a doctor may obtain drugs or appliances which he is required or entitled to supply under his terms of service), or

(*f*) in Northern Ireland, the sale or supply is to a doctor and in response to an order for a stock of medicinal products which are drugs referred to in paragraph 11(1)(*a*) of Schedule 1 to the Health and Personal Social Services (General Medical and Pharmaceutical Services) Regulations (Northern Ireland) 1973(**b**) (drugs and appliances to be supplied by the doctor for immediate administration or in other similar cases).

(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);

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

(*c*) orders or invoices referred to in paragraph (2)(*c*) or copies thereof; and

(*d*) orders referred to in column 3 of Schedule 4 to the Prescription Only Order (conditions for certain exemptions from the restrictions imposed by section 58), except orders referred to in paragraph 3 of Part I of that Schedule (drug testing schemes).

(4) In paragraph (3) "the 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*)—

(i) where the prescription only medicine was sold or supplied in accordance with a repeatable prescription, the date of the final sale or supply pursuant to that prescription, and

(ii) in every other case, the date on which the prescription only medicine was sold or supplied.

Record keeping in respect of certain veterinary drugs

7.—(1) Subject to paragraph (2), every person to whom the restrictions imposed by section 52 do not apply by virtue of Article 3(1) or Article 4(1) of the Veterinary Drugs Exemption Order shall make a record of every sale of a veterinary drug listed in Schedules 1, 2 and 3 to that order stating the particulars specified in paragraph (3).

(2) The requirement imposed by paragraph (1) shall not apply in respect of a sale for which there has been received an order containing the particulars specified in paragraph (3) or has been issued an invoice containing those particulars.

(3) The particulars referred to in paragraphs (1) and (2) are—

(*a*) the date on which 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; and

(**a**) S.I. 1974/506, to which there are no amendments relevant to the subject matter of these regulations.
(**b**) S.R. & O.(N. I.) 1973 No. 421.

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

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

Pack size on retail sale or supply of certain medicinal products on a general sale list

8.—(1) The conditions specified in paragraphs (2) and (3) are hereby prescribed for the purposes of section 53 (sale or supply of medicinal products on a general sale list) as conditions in accordance with which a business, so far as concerns the sale or supply of medicinal products, must be carried on.

(2) Where a medicinal product for human use containing aloxiprin, aspirin, paracetamol or salicylamide is sold by retail in the course of a business elsewhere than at a registered pharmacy or is so offered or exposed for sale by retail or so supplied in circumstances corresponding to retail sale, the product shall be presented for sale in a separate and individual container or package containing—

(*a*) in the case of effervescent tablets, not more than 30 tablets;

(*b*) in the case of tablets that are not effervescent, not more than 25 tablets; and

(*c*) in the case of powder or granules, not more than 10 sachets.

(3) Where a veterinary drug containing a substance listed in column 1 of Schedule 3 is sold by retail in the course of a business elsewhere than at a registered pharmacy or is so offered or exposed for sale by retail or so supplied in circumstances corresponding to retail sale, the veterinary drug shall be presented for sale in a separate and individual container or package containing not more than such quantity of capsules, tablets or powder, and not more than such volume or weight of the substance, as may be specified in column 2 of that Schedule in relation to that substance.

Offences

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

Revocations

10. The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1977 (**a**) and the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1978(**b**) are revoked.

(**a**) S. I. 1977/2132. (**b**) S. I. 1978/989.

Patrick Jenkin,
Secretary of State for Social Services.

27th November 1980.

Nicholas Edwards,
Secretary of State for Wales.

27th November 1980.

George Younger,
Secretary of State for Scotland.

1st December 1980.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 3rd December 1980.

(L. S.)

Peter Walker,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 8th day of December 1980.

(L. S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 5th day of December 1980.

(L. S.)

J. A. Young,
Permanent Secretary.

Regulation 5(1)

SCHEDULE 1

CLASSES OF PERSONS FOR THE PURPOSES OF REGULATION 5

Practitioners.

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

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) (wholesale dealer's licences) do not apply by virtue of an exemption conferred by or under the Act or by virtue of the provisions of section 48.

Ministers of the Crown and Government departments and officers thereof.

Regulation 6(1)

SCHEDULE 2

PARTICULARS IN PHARMACY RECORDS

1. Subject to paragraph 2, where the sale or supply of a prescription only medicine is either in pursuance of a prescription given by a practitioner or under Article 6(1) of the Prescription Only Order (emergency supply on doctor's undertaking to furnish prescription), the particulars referred to in regulation 6(1)(*a*) 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 the prescription;

(*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*) the date on the prescription; and

(*f*) in relation to the sale or supply of a prescription only medicine under Article 6(1) of the Prescription Only Order, the date on which the prescription relating to that sale or supply is received.

2. Where the sale or supply is in pursuance of a repeatable prescription and is not the first sale or supply in pursuance of that prescription the particulars referred to in regulation 6(1)(*a*) are either—

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

(ii) a reference to an entry in the register referred to in regulation 6(1)(*a*) which was made in respect of the first sale or supply in pursuance of that prescription and which contains the particulars specified in paragraph 1; or

(*b*) the particulars specified in paragraph 1.

3. Where the sale or supply of a prescription only medicine is a sale or supply under Article 6(3) of the Prescription Only Order (emergency supply of a limited quantity of medicine) the particulars referred to in regulation 6(1)(*a*) 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, or copy thereof, relating to it has been retained under regulation 6(2)(*c*), or where the sale or supply, although a sale by retail or a supply in circumstances corresponding to retail sale, is one to which the restrictions imposed by section 58(2) do not apply by reason of an exemption given otherwise than by Article 6 of the Prescription Only Order (emergency supply), the particulars referred to in regulation 6(1)(*a*) 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; and

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

SCHEDULE 3 *Regulation 8(3)*

PACK SIZES FOR CERTAIN VETERINARY DRUGS SOLD OR SUPPLIED BY RETAIL

Column 1	Column 2
Substance contained in the veterinary drug	Number of dosage units or weight or volume of substance per container or package
Aminonitrothiazole	100 millilitres of solution or 50 capsules
Aspirin	25 tablets or 25 sachets of powder
Bromhexine hydrochloride	20 grammes
Paracetamol	25 tablets
Phenylephrine hydrochloride	15 millilitres
Potassium chlorate	30 millilitres

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations consolidate, with amendments, the provisions of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1977 and its amending instruments, which are revoked. They also supersede the Medicines (General Sale List) Order 1977 (S.I. 1977/2129) to the extent that that order imposed limits on the pack size of medicinal products on a general sale list.

The provisions consolidated relate to the following matters:—

(*a*) requirements as 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 by certain sellers of veterinary drugs;

(*b*) restrictions as to the classes of persons to whom there may be sold prescription only medicines and pharmacy medicines, and exemptions from those restrictions; and

(*c*) 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 from automatic machines) and enforcement of regulations under section 66 of that Act relating to dealings with medicinal products.

The principal changes made by these regulations in relation to those matters are the removal of a provision whereby certain prescription only medicines could be sold to state registered physiotherapists by way of wholesale dealing, and the inclusion of an exemption from the requirement that a person lawfully conducting a retail pharmacy business keep certain records of sales and supplies of prescription only medicines, when the sale or supply is for the purposes of a drug testing scheme, or in response to certain orders from doctors under National Health Service arrangements in Scotland or Northern Ireland.

Under section 53 of the Medicines Act 1968, medicinal products on a general sale list may be sold or supplied by retail elsewhere than at a registered pharmacy only if certain conditions are fulfilled. These regulations prescribe conditions relating to the quantity of certain such products (both those for human use and veterinary drugs) that may be sold or supplied by retail in any one container or package. The limits imposed are similar to those which subsisted under the Medicines (General Sale List) Order 1977.

Regulation 9 makes it an offence to contravene regulations 3, 4, 6 or 7 of these regulations. A person who contravenes regulation 5 will be guilty of an offence under section 67(2) of the Medicines Act 1968 and a person who contravenes regulation 8 will thereby contravene section 53 of that Act and be guilty of an offence under section 67(5).

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