STATUTORY INSTRUMENTS

2000 No. 7

MEDICINES

The Retailers' Records for Veterinary Medicinal Products Regulations 2000

Made - - - - -	*7th January 2000*
Laid before Parliament	*10th January 2000*
Coming into force - -	*1st February 2000*

The Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to medicinal products, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

Title and commencement

1. These Regulations may be cited as the Retailers' Records for Veterinary Medicinal Products Regulations 2000 and shall come into force on 1st February 2000.

Interpretation

2.—(1) In these Regulations "the Act" means the Medicines Act 1968(**c**) and the term "veterinary medicinal product" is defined as in Article 1.2 of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**d**).

Record keeping for veterinary medicinal products

3.—(1) Any person who sells veterinary medicinal products by retail must comply with the requirements of paragraphs (2) to (4) below in relation to those products.

(2) For each incoming and outgoing transaction a record must be kept of—

(a) the date of the transaction,

(b) the identity of the product,

(c) the manufacturer's batch number,

(d) the quantity received or supplied,

(e) the name and address of the supplier or recipient, and

(f) where relevant, the name and address of the prescribing veterinarian and a copy of the prescription.

(3) At least once a year a detailed audit of all such transactions must be carried out and recorded, with incoming and outgoing products reconciled with those held in stock, and any discrepancies recorded.

(**a**) S.I. 1972/1811.
(**b**) 1972 c.68.
(**c**) 1968 c.67.
(**d**) OJ No. L317, 6.11.81, p.1.

(4) All records kept in accordance with the preceding paragraphs must be durable, but may be kept by electronic means, and must be kept for a period of three years from the date of the transaction or audit, and made available on request to a person duly authorised in writing by any person or body having a duty of enforcement given by regulation 5 below.

Application of regulation 3

4.—(1) Regulation 3 above only applies to the sale by retail of—

(a) veterinary medicinal products intended for administration to animals whose flesh or products are intended for human consumption and in respect of which a withdrawal period must be observed, and

(b) other veterinary medicinal products intended for administration to such animals unless the products are on a general sale list within the meaning of section 51(2) of the Act(**a**).

(2) Regulation 3 above does not apply to the sale by retail of a veterinary medicinal product by a person required to keep a record of the sale by virtue of an order made under section 57 of the Act(**b**) relating to veterinary drugs as defined in section 132(1) of the Act which is for the time being in force.

Enforcement

5.—(1) It is the duty of—

(a) the Minister of Agriculture, Fisheries and Food in relation to England,

(b) the Scottish Ministers in relation to Scotland,

(c) the National Assembly for Wales in relation to Wales, and

(d) the Department of Health, Social Services and Public Safety in relation to Northern Ireland,

to enforce the provisions of these Regulations.

(2) The Royal Pharmaceutical Society of Great Britain are under a duty concurrently with the Minister of Agriculture, Fisheries and Food in relation to England, the Scottish Ministers in relation to Scotland and the National Assembly for Wales in relation to Wales to enforce the provisions of these Regulations, except that this duty cannot be exercised in relation to the types of location specified in section 108(9) of the Act.

(3) Any duty of enforcement imposed by the preceding paragraphs is deemed to be a duty imposed by sections 108 to 110(**c**) of the Act as the case may be, and the provisions of sections 111 to 114 (other than sections 111(3) and 112(7)) and 119 of, and Schedule 3 to, the Act apply for the purposes of these Regulations as if they had been made under the Act, and as if an offence contrary to, and proceedings under, these Regulations were an offence and proceedings under the Act.

Offence and penalties

6.—(1) Any person who contravenes regulation 3 above is guilty of an offence and liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum, or

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(**a**) The current relevant order under section 51 is S.I. 1984/768.

(**b**) The current relevant order under section 57 is S.I. 1998/1044.

(**c**) In the case of section 108, the functions transferred to the Secretary of State in relation to Wales by S.I. 1978/272, were transferred to the National Assembly for Wales by article 2 of and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672. In the case of section 109, the functions of the Secretary of State in relation to Scotland were transferred to the Scottish Ministers by article 2 of and Schedule 1 to the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 1999, S.I. 1999/1750. In the case of section 110, references to the Ministers of Health and Social Services and of Agriculture for Northern Ireland were, by virtue of the Northern Ireland Constitution Act 1973 (c.36), section 40 and Schedule 5, and the Northern Ireland Act 1974 (c.28), section 1(3) and (4) (as last extended by S.I. 1998/1677) and Schedule 1, paragraph 2(1)(b), to be read as references to the relevant Northern Ireland Department. By virtue of section 22(2) of the Northern Ireland Act 1998, functions conferred on a Northern Ireland department by an enactment passed before the appointed day, 2nd December 1999 (in accordance with the Northern Ireland Act 1998 (Appointed Day) Order 1999, S.I. 1999/3208), continue to be exercisable by that department. The Department of Health and Social Services for Northern Ireland has been renamed as the Department of Health, Social Services and Public Safety by virtue of article 3(6) of the Departments (Northern Ireland) Order 1999, S.I. 1999/283 (N.I. 1).

(2) Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity he, as well as the body corporate, is guilty of that offence and liable to be proceeded against and punished accordingly.

(3) When the affairs of a body corporate are managed by its members the provisions of paragraph (2) above shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(4) In paragraphs (2) and (3) above references to a "body corporate" include references to a partnership in Scotland and, in relation to such partnership, any reference to a director or other officer of a body corporate is a reference to a partner.

Revocation

7. Regulation 6 of, and Schedule 2 to, the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**a**) (pharmacy records) shall be revoked in so far as they apply to retail sales of veterinary medicinal products.

Hayman
Minister of State,
6th January 2000 Ministry of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health

Hunt
7th January 2000 Parliamentary Under-Secretary of State, Department of Health

(**a**) S.I. 1980/1923, the relevant amending instrument is S.I. 1997/1831.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations complete the implementation of Article 50b.2 and .3 of Council Directive 81/851/EEC (OJ No. L317, 6.11.81. p. 1) on the approximation of the laws of the Member States relating to veterinary medicinal products as amended by Council Directive 90/676/EEC (OJ No. L373, 31.12.90, p. 15). Previous implementing provisions are in S.I. 1998/1044.

The Regulations impose requirements as to record keeping on retailers of veterinary medicinal products, subject to certain exemptions (regulations 3 and 4). Provision is made for enforcement, offences and penalties (regulations 5 and 6). Regulation 6 of, and Schedule 2 to, the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, which relate to pharmacy records, are revoked in so far as they apply to retail sales of veterinary medicinal products (regulation 7).

A Regulatory Appraisal has been prepared and a copy has been placed in the library of each House of Parliament. Copies may be obtained from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS.

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