STATUTORY INSTRUMENTS

1994 No. 2987

MEDICINES

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994

Made - - - -	*21st November 1994*
Laid before Parliament	*2nd December 1994*
Coming into force - -	*31st December 1994*

The Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) 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 Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994 and shall come into force on 31st December 1994.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968(**3**);

"homeopathic medicinal product" means a homeopathic veterinary medicinal product as defined in Article 1.1 of Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC, and laying down additional provisions on homeopathic veterinary medicinal products(**4**) or a homeopathic medicinal product as defined in Article 1.1 of Council Directive 92/73/EEC widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products(**5**);

(**1**) S.I.1972/1811.
(**2**) 1972 c. 68.
(**3**) 1968 c. 67.
(**4**) OJ No. L297, 13.10.92, p.12.
(**5**) OJ No. L297, 13.10.92, p.8.

"ready-made veterinary medicinal product" has the meaning given by Article 1.2 of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**6**) as amended by Council Directive 90/676/EEC(**7**); and

"veterinary medicinal product" has the meaning given by Article 1.2 of Council Directive 81/851/EEC as amended, and shall mean a veterinary medicinal product to which Article 2.1 of that Directive applies.

(2) Subject to paragraph (1) above, unless the context otherwise requires, expressions used in these Regulations shall be interpreted in accordance with Council Directive 81/851/EEC as amended.

Restriction on the administration of unlicensed veterinary medicinal products to animals

3. Subject to regulations 4 and 5 below, no person shall administer or cause or permit to be administered any veterinary medicinal product to an animal unless a product licence has been granted under the Act in respect of that product.

Exemptions

4.—(1) Nothing in regulation 3 above shall prohibit the administration of any veterinary medicinal product to an animal where it is administered for the purpose of—

(a) a medicinal test on animals in accordance with the provisions of section 32 or 33 of the Act, or in accordance with an animal test (confirmation of exemption) certificate issued under the Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986(**8**); or

(b) a test on animals in accordance with the provisions of a licence granted under the Animals (Scientific Procedures) Act 1986(**9**).

(2) Nothing in regulation 3 above shall prohibit the administration by a veterinary surgeon or by a person acting under his direction of a ready-made veterinary medicinal product imported and sold or supplied in accordance with the Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994(**10**).

Additional exemption

5.—(1) Subject to paragraphs (2) and (3) below, in the circumstances where no licensed veterinary medicinal product exists for a condition in a particular species, and where a veterinary surgeon considers it necessary to avoid causing unacceptable suffering to the animal or animals concerned, nothing in regulation 3 above shall prohibit him or a person acting under his direction from administering to a particular animal under his care or small number of such animals which are kept on the same premises—

(a) a veterinary medicinal product licensed for use in another animal species or for another condition in the same species; or

(b) if there is no product such as is referred to in subparagraph (a) above, a medicinal product licensed for use in human beings, or in respect of which a certificate of registration has been granted under the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994(**11**); or

(**6**) OJ No. L317, 6.11.81, p.1.
(**7**) OJ No. L373, 31.12.90, p.15. Council Directive 93/40/EEC (OJ No. L214, 24.8.93, p.31) makes further, unrelated, amendments to Council Directive 81/851/EEC.
(**8**) S.I. 1986/1180, amended by S.I. 1991/633.
(**9**) 1986 c. 14.
(**10**) S.I. 1994/2986.
(**11**) S.I. 1994/105, amended by S.I. 1994/899.

(c) if there is no product such as is referred to in subparagraph (b) above, a product prepared extemporaneously by any person authorised under the Act in accordance with the terms of a veterinary prescription.

(2) Where the carcase or part of the carcase or produce of an animal treated pursuant to paragraph (1) above will be sold or supplied for human consumption—

(a) the veterinary surgeon or a person acting under his direction shall administer a product which contains only substances to be found in a veterinary medicinal product licensed for use in food-producing animals;

(b) the veterinary surgeon shall, unless the product is a homeopathic medicinal product in which the level of active principles is equal to or less than one part per million, specify an appropriate withdrawal period; if no withdrawal period is indicated on the product for the species concerned, the veterinary surgeon shall specify a withdrawal period of not less than—

(i) 7 days for eggs,

(ii) 7 days for milk,

(iii) 28 days for meat from poultry and mammals including fat and offal, or

(iv) 500 degree days for meat from fish; and

(c) the veterinary surgeon shall keep a permanent record of—

(i) the date of examination of the animal,

(ii) the name and address of the owner,

(iii) the number of animals treated,

(iv) the diagnosis,

(v) the product prescribed,(vi)the dosage administered,

(vii) the duration of treatment, and

(viii) the recommended withdrawal period,and shall retain that record for a period of three years from the end of the calendar year to which such record relates.

(3) In the circumstances referred to in paragraph (1) above, nothing in that paragraph shall prohibit a veterinary surgeon or a person acting under his direction from administering to an animal or animals of a minor or exotic species any product such as is mentioned in sub-paragraphs (a) to (c) of that paragraph as he thinks fit, so long as no carcase or part of a carcase of, or any produce from, such animal will be sold or supplied for human consumption.

Enforcement

6.—(1) It shall be the duty of—

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

(b) the Secretary of State in relation to Scotland and Wales, and

(c) the Department of Health and Social Services for Northern Ireland in relation to Northern Ireland,

to enforce the provisions of these Regulations, and such duty shall be deemed to be a duty imposed by sections 108 to 110(**12**) of the Act as the case may be.

(**12**) In the case of section 108, the functions of the Minister of Agriculture, Fisheries and Food in relation to Wales were, by virtue of S.I. 1978/272, transferred to the Secretary of State. Other amendments to the section are not relevant to these Regulations. In the case of section 110, references to the Ministers of Health and Social Services and of Agriculture for Northern Ireland are, by virtue of the Northern Ireland Constitution Act 1973 (c. 36), section 40 and Schedule 5, and the

(2) The provisions of sections 108 to 114(**13**) and 119 of the Act shall apply for the purposes of these Regulations as if these Regulations had been made under that Act, and as if an offence contrary to, and proceedings under, these Regulations were an offence and proceedings under the Act.

Offences and penalties

7. If a person contravenes any provision of these Regulations he shall be guilty of an offence and—

(a) in the case of a contravention in relation to an animal where the carcase or part of the carcase or produce of that animal is intended for, or has been sold or supplied for, human consumption, he shall be liable on summary conviction to a fine not exceeding the statutory maximum or on conviction on indictment to a fine, or

(b) in any other case, he shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Due diligence defence

8. In any proceedings for an offence under these Regulations, it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of such an offence by himself or by a person acting under his direction.

Offences by bodies corporate

9.—(1) 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, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) When the affairs of a body corporate are managed by its members the provisions of paragraph (1) 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.

(3) In paragraphs (1) and (2) 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.

Amendment of section 9 of the Act

10.—(1) Section 9 of the Act (exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners) shall be amended as follows.

(2) In subsection (3), after paragraph (c) there shall be inserted the words "or

(d) in relation to a ready-made veterinary medicinal product as defined in Article 1.2 of the 1981 Directive.".

Northern Ireland Act 1974 (c. 28), section 1(3) and (4) (as last extended by S.I. 1993/1753) and Schedule 1, paragraph 2(1)(b), to be read as references to the relevant Northern Ireland Department.

(**13**) Subsection (2) of section 114 was amended by the Criminal Justice Act 1982 (c. 48), sections 37 and 46, to insert a reference to level 3 on the standard scale, and subsection (3) thereof was amended by the Magistrates' Courts Act 1980 (c. 43), section 32(2), to insert a reference in paragraph (a) to the prescribed sum.

Amendment of section 10 of the Act

11.—(1) Section 10(**14**) of the Act (exemptions for pharmacists) shall be amended as follows.

(2) After subsection (6) there shall be inserted the following subsection:—

"(6A) The preceding provisions of this section shall not have effect so as to exempt from the restrictions imposed by sections 7 and 8 of this Act anything done in a registered pharmacy by or under the supervision of a pharmacist in relation to a ready-made veterinary medicinal product as defined in Article 1.2 of the 1981 Directive.".

Amendment of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972

12. The Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(**15**) shall be amended by the insertion in article 2 of the following new paragraph:—

"(7) Nothing in paragraphs (1)(b), (c)(ii) and (iii) or (3) above shall be taken to exempt from the restrictions imposed by section 7 of the Act anything done by a veterinary surgeon or veterinary practitioner or in a registered pharmacy in relation to a ready-made veterinary medicinal product as defined 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(**16**) as amended by Council Directive 90/676/EEC(**17**).".

Amendment of the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991

13. The Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991(**18**) shall be amended as follows:

(a) in regulation 2(1) (interpretation), in the definition of "veterinary medicinal product", for the words "the Medicines (Restriction on the Administration of Veterinary Medicinal Products) Regulations 1983", there shall be substituted "the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994", and sub-paragraph (c) of the definition shall be omitted; and

(b) in regulation 4 (Prohibition on administration to animals of unlicensed substances)—

(i) in paragraph (2), for the words after the word "administered" to the end of the paragraph there shall be substituted "in accordance with an exemption specified in regulation 4 or 5 of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994.", and

(ii) paragraph (3)(b) shall be omitted.

Revocation

14. The Medicines (Restriction on the Administration of Veterinary Medicinal Products) Regulations 1983(**19**) are hereby revoked.

(**14**) Subsection (4) of section 10 was amended, and subsections (5) and (6) were added by S.I. 1971/1445. S.I. 1993/834 makes a further amendment to section 10 which is not relevant to these Regulations.
(**15**) S.I. 1972/1200, to which there are amendments not relevant to these Regulations.
(**16**) OJ No. L317, 6.11.81, p.1.
(**17**) OJ No. L373, 31.12.90, p.15.
(**18**) S.I. 1991/2843, amended by S.I. 1993/990 and 1994/2465.
(**19**) S.I. 1983/1732.

Tom Sackville
Parliamentary Under Secretary of State,21st November 1994

Department of Health

Ministry of Agriculture,
Fisheries and Food
17th November 1994

Angela Browning
Parliamentary Secretary,

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Article 4.1 (part), 4.3 (part), 4.4 and 4.5 (part) of Council Directive 81/851/EEC (OJNo. L317, 6.11.81, p.1) on the approximation of the laws of the Member States relating to veterinary medicinal products ("the Directive") as amended by Council Directive 90/676/EEC (OJ No. L373, 31.12.90, p.15), and Article 2.1 (part) of Council Directive 92/74/EEC (OJ No. L297, 13.10.92, p.12) widening the scope of Directive 81/851/EEC and laying down additional provisions on homeopathic veterinary medicinal products.

The Regulations prohibit the administration of unlicensed veterinary medicinal products to animals except for specified purposes such as medicinal tests or where the Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994 apply (regulation 4) or in specified circumstances to avoid causing unacceptable suffering to an animal (regulation 5). Additional rules apply where unlicensed products are administered to food-producing animals (regulation 5(2)), but less restrictions are applied in the case of treatment of minor or exotic species which are non-food-producing (regulation 5(3)).

The Regulations are to be enforced by the Ministers having a duty to enforce the provisions of the Medicines Act 1968 and each of those Ministers is then an "enforcement authority" under the Act (regulation 6(1)). Certain enforcement provisions of the Act are applied and offences and penalties are prescribed (regulations 6(2) and 7 to 9).

The Regulations make consequential amendments to sections 9 and 10 of the Medicines Act 1968 so as to provide that the exemptions from licensing granted to veterinary surgeons, veterinary practitioners and pharmacists do not extend to anything done in relation to ready-made veterinary medicinal products, which the Directive requires to be licensed. The only unlicensed products permitted to be administered to animals are as provided by the Directive and reflected in these Regulations, which include in certain circumstances products prepared extemporaneously, known as "veterinary specials" (regulations 10 and 11). The Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 is amended accordingly (regulation 12). The Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991 are also amended so as to allow an unlicensed substance within the meaning of those Regulations to be administered in accordance with the exemptions in these Regulations, and a further consequential amendment is made to the definition of "veterinary medicinal product" (regulation 13).

The Medicines (Restriction on the Administration of Veterinary Medicinal Products) Regulations 1983 are revoked (regulation 14).

A Compliance Cost Assessment has been prepared and a copy has been placed in the library of each House of Parliament.