STATUTORY INSTRUMENTS

1997 No. 2884

MEDICINES

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Amendment Regulations 1997

Made - - - -	*4th December 1997*
Laid before Parliament	*8th December 1997*
Coming into force - -	*1st February 1998*

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) Amendment Regulations 1997 and shall come into force on 1st February 1998.

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

2. The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**3**) shall be amended in accordance with the following regulation.

3. For regulations 2 to 5 there shall be substituted regulations 2 to 5 as follows:

"**Interpretation**

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968(**4**);

"administer" includes import for the purposes of administration and cognate expressions shall be construed accordingly;

(**1**) S.I.1972/1811.
(**2**) 1972 c. 68.
(**3**) S.I. 1994/2987, relevant amendments are S.I. 1994/3142, 3144 and 1997/322.
(**4**) 1968 c. 67.

"authorised veterinary medicinal product" means a veterinary medicinal product—

(a) which has a marketing authorisation within the meaning of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**5**),

(b) the administration of which has been authorised by the Ministers as defined in the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 in accordance with Article 4.1, 2nd paragraph, of Directive 81/851 or allowed by those Ministers in accordance with Article 4.1, 3rd paragraph, of that Directive,

(c) which has a product licence under the Act, or

(d) which is registered under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997(**6**);

"Directive 81/851" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**7**) as amended by Council Directive 90/676/EEC(**8**);

"homeopathic medicinal product" means a homeopathic veterinary medicinal product as defined in Article 1.1 of Council Directive 92/74/EEC(**9**) or a homeopathic medicinal product as defined in Article 1.1 of Council Directive 92/73/EEC(**10**); and

"medicinal product authorised for use in human beings" means a medicinal product—

(a) which has a marketing authorisation within the meaning of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**11**),

(b) which has a product licence under the Act for use in human beings, or

(c) which has a certificate o registration under the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994(**12**).

(2) The terms "veterinary medicinal product" and "ready-made veterinary medicinal product"are defined in Article 1.2 of Directive 81/851 and other expressions used in these Regulations shall, subject to paragraph (1) above and unless the context otherwise requires, be interpreted in accordance with that Directive.

Restriction on the administration of unauthorised 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 that product is an authorised veterinary medicinal product.

Exemptions

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

(**5**) S.I. 1994/3142, amended by S.I. 1997/1729.
(**6**) S.I. 1997/322.
(**7**) OJ No. L317, 6.11.81, p.1.
(**8**) 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.
(**9**) Widening the scope of Directive 81/851/EEC, and laying down additional provisions on homeopathic veterinary medicinal products (OJ No. L297, 13.10.92, p. 12).
(**10**) 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 (OJ No. L297, 13.10.92, p. 8).
(**11**) S.I. 1994/3144.
(**12**) S.I. 1994/105, amended by S.I. 1994/899.

(a) a medicinal test on animals in accordance with section 32 or 33 of the Act, or in connection with that test, where the product is authorised in accordance with Directive 81/851 elsewhere than in the United Kingdom and is administered for the purpose of comparing the efficacy of the product the subject of the test, or

(b) a test on animals in accordance with the provisions of a licence granted under the Animals (Scientific Procedures) Act 1986(**13**).

(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(**14**).

Additional exemption

5.—(1) Subject to paragraphs (2) and (3) below, in the circumstances where no authorised 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 a small number of such animals which are kept on the same premises—

(a) a veterinary medicinal product authorised 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 authorised for use in human beings, or

(c) if there is no product such as is referred to in subparagraph (b) above, a product prepared extemporaneously by any person lawfully authorised in the United Kingdom to do so, 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 is intended for human consumption—

(a) the veterinary surgeon or person acting under his direction shall administer a product which contains only substances to be found in a veterinary medicinal product authorised 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, which shall be the period indicated on the product for the species concerned, or, if none, a 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,

(**13**) 1986 c. 14.
(**14**) S.I. 1994/2986, amended by S.I. 1994/3142.

(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 subparagraphs (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 is intended for human consumption.".

Amendment of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

4. Paragraph 32 of Schedule 5 to the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, paragraph 22 of Schedule 7 to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and regulation 37 of and Schedule 6 to the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 shall be revoked.

Signed by authority of the Secretary of State for Health

Jay
Minister of State,
Department of Health

4th December 1997

Jeff Rooker
Minister of State, Ministry of Agriculture,
Fisheries and Food

2nd December 1997

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations consolidate, with amendments, regulations 2 to 5 of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, which implemented in part 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 as amended by Council Directive 90/676/EEC (OJ No. L373, 31.12.90, p. 15) and in part 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 principal amendments are made to implement—

(a) the judgment of the European Court of Justice in case *C—297/94 Dominique Bruyere and Others v. Belgium* to provide that the prohibition on administration of unauthorised veterinary medicinal products includes a prohibition on importation of such products for the purpose of administration (amended regulation 2(1)) and

(b) Title I, Part 4, Chapter II.1, 2nd paragraph of the Annex to Council Directive 81/852/EEC (OJ No. L317, 6.11.81, p. 16) on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products, as amended by Commission Directive 92/18/EEC (OJ No. L97, 10.4.92, p. 1), to allow a product authorised in accordance with Council Directive 81/851/EEC elsewhere than in the United Kingdom to be administered as part of an animal test when it is to be used as a comparison with a product the subject of the test (amended regulation 4(1)(a)).

Consequential amendments are made to the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 (regulation 4).