Statutory Instrument 2000 No. 776

The Marketing Authorisations for Veterinary Medicinal Products Amendment Regulations 2000

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STATUTORY INSTRUMENTS

2000 No. 776

MEDICINES

The Marketing Authorisations for Veterinary Medicinal Products Amendment Regulations 2000

Made	*14th March 2000*
Laid before Parliament	*21st March 2000*
Coming into force	*14th April 2000*

The Minister of Agriculture, Fisheries and Food and the Secretary of State, 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 Marketing Authorisations for Veterinary Medicinal Products Amendment Regulations 2000 and shall come into force on 14th April 2000.

Amendment of the Marketing Authorisations for Veterinary Medicinal Products

Regulations 1994

2. - (1) The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994[3] shall be amended in accordance with the following paragraphs.

(2) In regulation 1 (title, commencement and interpretation),

(a) in paragraph (1)-

(i) in the entry for "Council Regulation 2309/93/EEC", for those words there shall be substituted "Council Regulation (EEC) No. 2309/93", and the word "and" at the end shall be omitted, and

(ii) after the entry for "Council Directive 93/40/EEC" the following entries shall be inserted:

" Commission Regulation (EC) No. 649/98 amending the Annex to Council Regulation (EEC) No. 2309/93[4]; and

Commission Directive 1999/104/EC amending the Annex to Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products[5];"

(b) for paragraph (6) there shall be substituted the following paragraph:

" (6) Unless the context requires otherwise any reference in these Regulations to a Community instrument is to that instrument as amended as at the time the Marketing Authorisations for Veterinary Medicinal Products Amendment Regulations 2000 were made, except that references to Council Directive 81/852/EEC in relation to applications for marketing authorisations made before 1st October 2000 are references to that Directive not amended by Commission Directive 1999/104/EC." and

(c) in paragraph (4) for the words "Council Regulation 2309/93/EEC" there shall be substituted "Council Regulation (EEC) No. 2309/93".

(3) In regulation 3 (placing veterinary medicinal products on the market)-

(a) for the words "or have in his possession for the purposes of placing on the market," there shall be substituted "or import for the purposes of placing on the market or have in his possession for those purposes,"; and

(b) for the words "Council Regulation 2309/93/EEC" there shall be substituted " Council Regulation (EEC) No. 2309/93".

(4) In regulation 6(1) (duties on persons responsible for placing products on the market), the word "and" after sub-paragraph (d) shall be omitted and at the end of sub-paragraph (e) the word "and" and the following new sub-paragraph shall be inserted:

" (f) from 1st June 2001, paragraph C.a of Title I, Part 2 (for veterinary medicinal products other than immunological veterinary medicinal products) or paragraph C.a of Title II, Part 6 (for immunological veterinary medicinal products) of the Annex to Council Directive 81/852/EEC.".

(5) In regulation 18(1) (application of the Medicines Act 1968 to marketing authorisations), after the words "placing on the market" there shall be inserted ", or import for those purposes,".

Hayman
Minister of State, Ministry of Agriculture, Fisheries and Food

13th March 2000

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State, Department of Health

14th March 2000

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 so as to implement:

(a) Commission Directive 1999/104/EC amending the Annex to Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products, concerning the prevention of the transmission of animal spongiform encephalopathies in relation to veterinary medicinal products (regulation 2(2)(a)(ii), (b) and (4)),

(b) Commission Regulation (EC) No. 649/98 amending the Annex to Council Regulation (EEC) No. 2309/93, so as to make an amendment to the types of veterinary medicinal products which may be authorised by the Community in accordance with Part B (regulation 2(2)(a)(ii)), and

(c) the judgment of the European Court of Justice in case *C-297/94 Dominique Bruyere and Others v. Belgium*, in so far as it relates to placing on the market, so as to prohibit importation of an unauthorised veterinary medicinal product for the purposes of placing it on the market (regulation 2(3) and (5)).

Other minor amendments are also made.

Notes:

[1] S.I. 1972/1811.back

[2] 1972 c. 68.back

[3] S.I. 1994/3142, to which there are amendments not relevant to these Regulations.back

[4] OJ No. L88, 24.3.98, p. 7.back

[5] OJ No. L3, 6.1.2000, p. 18.back

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