2001 No. 1669

MEDICINES

The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2001

Made - - - - -	*2nd May2001*
Laid before Parliament	*3rd May 2001*
Coming into force - -	*27th May 2001*

The Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England, the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, acting jointly, with the consent of the Treasury, in exercise of the powers conferred by section 1(1), (2) and (3)(b) of the Medicines Act 1971(**a**) and now vested in them(**b**) 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 these Regulations(**c**), and the Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated(**d**) for the purpose of section 2(2) of the European Communities Act 1972(**e**) in relation to medicinal products and the common agricultural policy of the European Community, 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 (Products for Animal Use—Fees) (Amendment) Regulations 2001 and shall come into force on 27th May 2001.

(**a**) 1971 c. 69 as amended by section 21 of the Health and Medicines Act 1988 (c. 49); by virtue of section 1(3) of the 1971 Act expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67) as amended by article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388). The expression "the Ministers" is defined in section 1(1) of the 1968 Act as so amended.

(**b**) In the case of the Minister of Agriculture, Fisheries and Food (so far as concerns functions previously vested in the Secretaries of State respectively concerned with agriculture in Scotland and—in consequence of S.I. 1978/272—Wales), by virtue of articles 2(2) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142); in the case of the Secretary of State concerned with health in England (so far as concerns functions previously vested in the Secretaries of State respectively concerned with health in Scotland and—in consequence of S.I. 1969/388—Wales), by virtue of articles 2(1) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999; in the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) and article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283 (N.I. 1)).

(**c**) *See* section 129(6) of the Medicines Act 1968 as extended to include Regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

(**d**) S.I. 1972/1811.

(**e**) 1972 c. 68.

Amendment of the previous Regulations

2.—(1) The Medicines (Products for Animal Use—Fees) Regulations 1998(**a**) shall be amended in accordance with the remainder of this regulation.

(2) In regulation 2(1) (interpretation), at the end of the definition of "Regulation (EC) No. 541/95" there shall be inserted the words "as amended by Commission Regulation (EC) No. 1146/98(**b**)" and after the definition of "third country", there shall be inserted the following definitions—

> ""TSE Directive" means 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(**c**);
>
> "TSE variation application" means an application (other than a complex application as defined in Schedule 1 or an application which seeks to demonstrate compliance by cross-referring to data held by the relevant authority) to vary—
>
> (a) a marketing authorisation to comply with regulation 6(1)(f) of the Marketing Authorisation Regulations 1994(**d**); or
>
> (b) a product licence to render unnecessary the service of a notice under section 24(1A) of the Act to bring about the expiry of the licence for failure to comply with the criteria of the Annex to the TSE Directive;".

(3) At the end of regulation 5(1) (applications for variation of marketing authorisations etc), there shall be added the words "unless the application is covered by regulation 7".

(4) For regulation 7 (variation at the invitation of the relevant authority), there shall be substituted the following regulation:

> **Variation applications for which no fee is payable**
>
> **7.** No fee is payable in respect of—
>
> (a) a TSE variation application; or
>
> (b) an application for a variation made at the express written invitation of the relevant authority.

(5) In Schedule 1, Part I (interpretation), in the definition of "emergency vaccine application", the words "marketing authorisation or" shall be deleted.

(6) In Schedule 1, Part II (application fees), in Table A, opposite the words "emergency vaccine application" in column (1), there shall be deleted from column (2) the figure "£40".

(7) In Schedule 1, Part IV (variation fees), in column (1) of Table E, in the third item, the words "authorisation or" shall be deleted.

(**a**) S.I. 1998/2428 amended by S.I. 1999/2512, 2000/2250.
(**b**) OJ No. L159, 3.6.98, p. 31.
(**c**) OJ No. L3, 6.1.2000, p. 18.
(**d**) S.I. 1994/3142; the relevant amendment is made by S.I. 2000/776.

(8) In Schedule 7 (waiver, reduction or refund of fees)—

(a) in paragraph 2(a), there shall be inserted after the word "granted", the words "or varied" and in paragraph 2(b) there shall be inserted after the word "for" at the first place where it occurs, the words ", or for a variation of,"; and

(b) at the end of paragraph 4, there shall be inserted the following sub-paragraph—

"(3) Where a TSE variation application has been made before the coming into force of the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2001 the relevant authority shall refund or, where no payment has been made, waive any fee payable in connection with that application under regulation 5.".

Hayman
Minister of State
25th April 2001 Ministry of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State
25th April 2001 Department of Health

Bairbre de Brún
Minister of Health, Social Services and
1st May 2001 Public Safety

Bríd Rodgers
Minister of Agriculture and
2nd May 2001 Rural Development

We consent

Jan Dowd and Greg Pope
2nd May 2001 Two of the Lords Commissioners of Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Animal Use—Fees) Regulations 1998 as amended by the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 1999 and the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2000. The 1998 Regulations prescribe fees in connection with applications and inspections relating to:

(a) marketing authorisations under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S.I. 1994/3142);

(b) licences and certificates granted under the Medicines Act 1968 in so far as they apply to medicinal products for animal use; and

(c) the registration of homoeopathic veterinary medicinal products.

In prescribing fees in relation to the 1994 Regulations, the 1998 Regulations as amended by these Regulations continue to supplement the 1994 Regulations in implementing Council Directive 93/40/EEC (OJ No. L214, 24.8.93, p. 31) which contains amendments to Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p. 1).

The main amendment is a replacement which adds to regulation 7 of the 1998 Regulations: as well as fees not being payable where a variation is applied for at the express request of the relevant authority, they will not be payable in respect of applications to vary marketing authorisations and product licences to comply with the requirements of Commission Directive 1999/104/EC (OJ No. L3, 6.1.2000, p. 18) which amends Council Directive 81/852/EEC (OJ No. L317, 6.11.81, p. 16) to specify measures for the prevention of the transmission of animal spongiform encephalopathies.

A Regulatory Impact Assessment 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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