This statutory instrument has been printed to correct errors in S.I. 2004/2750 and is being issued free of charge to all known recipients of that instrument.

STATUTORY INSTRUMENTS

2004 No.3081

MEDICINES

The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2004

Made - - - -	*16th November 2004*
Laid before Parliament	*24th November 2004*
Coming into force - -	*17th December 2004*

The Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, with the consent of the Treasury, in exercise of the powers conferred upon them by section 1(1), (2) and (3)(b) of the Medicines Act 1971(**a**) and now vested in them(**b**);

And the Secretary of State, being designated for the purposes of section 2(2) of the European Communities Act 1972(**c**) in relation to medicinal products(**d**), in exercise of the powers conferred on her by that section;

And in exercise of the powers conferred by section 56 of the Finance Act 1973(**e**), and with the consent of the Treasury;

After carrying out a consultation with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations in accordance with section 129(6) of the Medicines Act 1968(**f**);

(**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 Medicines Act 1971 expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67) (see the following footnote).

(**b**) "The Ministers" is defined in section 1(1) of the Medicines Act 1968 (following amendment by article 5(1) and paragraph 15(3) of Schedule 1 to the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794)) as the Secretary of State acting jointly with the Ministers for Northern Ireland specified in paragraphs (a) and (b) of section 1(1) namely the Minister of Health and Social Services for Northern Ireland and the Minister of Agriculture for Northern Ireland. Section 95(5) of and paragraph 10(1)(b) of Schedule 12 to the Northern Ireland Act 1998 (c.47) provides that references in existing legislation to a minister in charge of a particular Northern Ireland Ministry are to be construed as references to the Northern Ireland Minister in charge of that Northern Ireland Department. The Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland were renamed the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development respectively by article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283 (N.I. 1) and retained their previous functions by virtue of section 95(5) of the 1998 Act. Paragraph 4(1)(b) of the Schedule to the Northern Ireland Act 2000 (c. 1) has effect during suspension of devolved government pursuant to section 1(8) of that Act: it provides that the functions of a Northern Ireland Minister who was in charge of a Northern Ireland Department immediately before the coming into force of section 1 of the Act may be discharged by that Department subject, according to paragraph 4(1)(f) of the Schedule, to the direction and control of the Secretary of State. Section 1(8) of the 2000 Act is in force by virtue of article 2 of the Northern Ireland Act (Suspension of Devolved Government) Order 2002 (S.I. 2002/2574).

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

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

(**e**) 1973 c. 51.

(**f**) 1968 c. 67. This subsection applies by virtue of section 1(3) of the Medicines Act 1971.

And after carrying out the consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety)(**a**);

Make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2004 and shall come into force on 17th December 2004.

Amendment of the Schedules to the Medicines (Products for Animal Use—Fees) Regulations 2004

2.—(1) The Schedules to the Medicines (Products for Animal Use—Fees) Regulations 2004(**b**) shall be amended as specified in this regulation.

(2) In Part 3 of Schedule 1, after 'below' in both paragraphs 1(1) and 2(1) insert, "plus, where applicable, the fee in the third column for the sixth and each additional Member State to which it applies".

(3) In Schedule 2, for paragraph 3, substitute:

> "**3.**—(1) Paragraph 2 does not apply to an inspection concerned only with quality control relating to a biological product (not being a dormant biological product), in which case the fee is £1,480.
>
> (2) Neither paragraph 2 nor sub-paragraph (1) applies to such an inspection of such a product for which a marketing authorisation or product licence was granted because it was identical to an existing product, in which case the fee is £65.
>
> (3) Where an inspection relating to a biological product (not being a dormant biological product) concerns both quality control and other matters, the fee payable is that under both paragraph 2 and this paragraph.".

(4) In Schedule 4, after paragraph 2 and its table, insert:

> "**2A.**—(1) Paragraph 2 does not apply where a registration application relates to a product—
>
> (a) already granted a registration certificate on account of equivalence to another product, pursuant to Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**c**); or
>
> (b) which is registered or authorised in an EEA State under legislation which implements the provisions of Article 16 of Directive 2001/82/EC in that State.
>
> (2) Where sub-paragraph (1) applies the application fee shall be—
>
> (a) £130 for a product prepared from not more than 5 homoeopathic stocks; and
>
> (b) £305 for a product prepared from more than 5 homoeopathic stocks.".

Transitional provisions

3.—(1) These Regulations shall not apply in respect of any application made before the date these Regulations come into force.

(**a**) OJ No. L31, 1.2.2002, p. 1.
(**b**) S.I. 2004/2750.
(**c**) S.I. 1994/105.

(2) Paragraph (1) does not apply where an inspection is made after the date these Regulations come into force in connection with an application made before that date, in which case the inspection fee payable is that due under these Regulations.

Ben Bradshaw
Parliamentary Under Secretary of State,
11th November 2004 Department for Environment, Food and Rural Affairs

L.S.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

D C Gowdy
Permanent Secretary,
11th November 2004 Department of Health, Social Services and Public Safety

L.S.

Sealed with the Official Seal of the Department of Agriculture and Rural Development

Pat Toal
Permanent Secretary,
11th November 2004 Department of Agriculture and Rural Development

We consent.

Joan Ryan
Nick Ainger
16th November 2004 Two of the Lords Commissioners of Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations amend the Medicines (Products for Animal Use—Fees) Regulations 2004 ('the principal Regulations') (S.I. 2004/2750) which 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 under the Medicines Act 1968 insofar as they apply to medicinal products for animal use; and

(c) the registration of homoeopathic veterinary medicinal products under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 (S.I. 1997/322).

Regulation 2(2) corrects an error introduced by the principal Regulations, relating to the fees for applications for assistance in connection with mutual recognition applications: the principal Regulations provided that the first such application made in each six-month cycle after grant would incur only a basic fee. These regulations provide that an additional charge for the sixth and each additional Member State covered by such applications is also payable.

Regulation 2(3) corrects an error introduced by the principal Regulations relating to the inspection fees for biological products. The principal Regulations arguably provided that the only inspection fees payable for such products were those set out in paragraph 3 of Schedule 2 where the circumstances described in that paragraph applied. The effect of these Regulations is that the fees for inspections of biological products are those set out in paragraph 2 of that Schedule, unless paragraph 3 applies.

Regulation 2(4) corrects an omission from the principal Regulations relating to application fees for registration of homoeopathic veterinary medicinal products. This regulation reduces the fees payable in the circumstances described from £620 and £800, depending on the number of homoeopathic stocks contained, as taken from the 'any other application' row of the table in paragraph 2 of Schedule 4 of the principal Regulations, to £130 and £305 respectively.

Regulation 3 (transitional provisions) provides that the Regulations (save for the exception in paragraph (2) of that regulation) only apply to applications made after the Regulations come into force.

A Regulatory Impact Assessment was prepared for the principal Regulations 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, Addlestone, Surrey, KT15 3LS. No new assessment was prepared since these Regulations introduce no additional impacts on the cost of business to those envisaged when the principal Regulations were made.

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