STATUTORY INSTRUMENTS

1991 No. 2063

MEDICINES

The Medicines (Fees Relating to Medicinal Products for Animal Use) (Amendment) Regulations 1991

Made - - - -	*12th September 1991*
Laid before Parliament	*13th September 1991*
Coming into force - -	*4th October 1991*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of the powers conferred by section 1(1) and (2) of the Medicines Act 1971(**1**) and now vested in them(**2**) 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(**3**), hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Medicines (Fees Relating to Medicinal Products for Animal Use) (Amendment) Regulations 1991 and shall come into force on 4th October 1991.

Amendments

2.—(1) The Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1991(**4**) shall be amended in accordance with the following provisions of this regulation.

(**1**) 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 the Transfer of Functions (Wales) Order 1969 (S.I.1969/388). The expression Ministers is defined in section 1(1) of the 1968 Act as so amended.

(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969; in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) 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.

(**4**) S.I. 1991/632.

(2) In regulation 2(1) (interpretation) the definition of "inactive biological medicinal product" shall be deleted.

(3) For paragraph (b) in regulations 3, 5 and 8 respectively there shall be substituted the following paragraph—

"(b) in respect of any inspection specified in Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.".

(4) In regulation 10 (inspections of a site) for the words "paragraphs 2, 3, 4 and 6 of Schedule 2" there shall be substituted the words "paragraphs 2 to 6 of Schedule 2".

(5) In regulation 16(1) (late payment of annual fees) for the words "one month" there shall be substituted the words "three months".

(6) For Part III of Schedule 1 (fees for applications for variations of licences or certificates) there shall be substituted Part III as set out in the Schedule to these Regulations.

(7) In Schedule 2 (fees for inspections)—

(a) in paragraph 1(1) (interpretation) before the definition of "major inspection" there shall be inserted the following definition—

""dormant biological medicinal product" means a product which is not currently being manufactured or sold and in respect of which there is no current intention to recommence the manufacture or sale;";

(b) in paragraph (5) for the words "an inactive biological medicinal product" there shall be substituted the words "a dormant biological medicinal product".

(8) In Schedule 4—

(a) in Part I, paragraph 5 for the words "paragraph 5 of Part II of this Schedule" there shall be substituted the words "paragraph 4 of Part II of this Schedule";

(b) in Part III for the words "paragraph 2 of Part I" there shall be substituted the words "the provisions of Part I of this Schedule".

(9) In paragraph 1 of Schedule 5 the words "in accordance with paragraph 5(a) of Part I of Schedule 4"(**5**) shall be deleted.

Virginia Bottomley
12th September 1991 Minister of State for Health

David Hunt
6th September 1991 Secretary of State for Wales

Allan Stewart
Parliamentary Under Secretary of State, Scottish
5th September 1991 Office

(**5**) These words were inserted by a correction slip to S.I. 1991/632.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 2nd September 1991.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland 29th September 1991.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland 30th September 1991.

L.S.

W. J. Hodges
Permanent Secretary

We consent,

Sydney Chapman
Irvine Patnick
Two of the Lords Commissioners of Her Majesty's Treasury

9th September 1991

SCHEDULE regulation 2(6).

"PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

Product licences

1. The fee payable under regulation 5(a) in connection with an application for variation of a product licence—

(a) in the case of a complex application, shall be £1,050;

(b) in any other case—

(i) requiring veterinary, scientific or pharmaceutical assessment–

(aa) for a variation, shall be £315;

(bb) for any other consequential variation to other licences, in identical terms, shall be £105;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £105 in respect of each variation;

(iii) where the variation applied for involves the reissue of the product licence in the new name of the company, shall be £105;

(iv) where the product licence relates solely to an emergency vaccine, shall be £30.

Manufacturers' licences

2. The fee payable under regulation 5(a) in connection with an application for variation of a manufacturer's licence—

(a) in the case of a manufacturer's licence referred to in paragraph 5(2) of Part II of this Schedule, shall be £85;

(b) in any other case—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £325;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £90.

Wholesale dealers' licences

3. The fee payable under regulation 5(a) in connection with an application for variation of a wholesale dealer's licence—

(a) requiring veterinary, scientific or pharmaceutical assessment, shall be £325;

(b) not requiring veterinary, scientific or pharmaceutical assessment, shall be £90.

Animal Test Certificates

4. The fee payable under regulation 5(a) in connection with an application for variation of—

(a) an animal test certificate—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £315;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £105;

(iii) where the variation applied for involves the reissue of the animal test certificate in the new name of the company, shall be £105; or

(b) an animal test (confirmation of exemption) certificate—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £300;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £85;

(iii) where the variation applied for involves the reissue of the animal test (confirmation of exemption) certificate in the new name of the company, shall be £85."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1991 in order to correct minor drafting errors.

In addition—

(1) payment of the annual fee is now required within three months (formerly one month) of the due date, before the further fee for late payment becomes payable (regulation 2(5));

(2) the provisions relating to fees for applications for variations of licences or certificates have been simplified with some slight reductions in the level of fees (regulation 2(6)).