
STATUTORY INSTRUMENTS

1996 No. 2196

MEDICINES

The Medicines (Products for Animal Use — Fees) (Amendment) Regulations 1996

Made - - - - *21st August 1996*
Laid before Parliament *23rd August 1996*
Coming into force - - *13th September 1996*

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:

Title and commencement

1. These Regulations may be cited as the Medicines (Products for Animal Use — Fees) (Amendment) Regulations 1996 and shall come into force on 13th September 1996.

Amendment of the Medicines (Products for Animal Use — Fees) Regulations 1995

2. The Medicines (Products for Animal Use — Fees) Regulations 1995(4) shall be amended in accordance with regulations 3 to 7 below.

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- (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 “the 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.1995/2364.

3. In regulation 2(1) (Interpretation) in the definition of “complex application” for the words “a marketing authorisation, product licence or animal test certificate” there shall be substituted the words “a marketing authorisation or product licence”.

4. In Schedule 1, in Part I (Interpretation), after the definition of “category III application” there shall be inserted the following definition:

““food-producing animals” means animals whose flesh or products are intended for human consumption;”

5. In Schedule 1, Part II, for paragraph 6 (fees for applications for animal test certificates), there shall be substituted the following paragraph:

“6. The fee for an application for an animal test certificate in relation to a medicinal product, other than a biological product, which is for administration to food-producing animals shall be £600, and in any other case shall be £250..”

6. In Schedule 1, Part IV, for paragraph 6 (fees for an application for the variation of an animal test certificate), there shall be substituted the following paragraph:

“6.—(1) The fee for an application for the variation of an animal test certificate shall be £200..”

7. In Schedule 1, Part V, paragraph 3 (fee for an application for renewal of an animal test certificate), for the figure “£525” there shall be substituted the figure “£90”.

Transitional provision

8. Nothing in these Regulations shall apply to an application made before the date these Regulations come into force.

Signed by authority of the Secretary of State for Health

Department of Health
16th August 1996

Gerald Malone
Minister of State,

Signed by authority of the Secretary of State for Wales

Welsh Office
21st August 1996

Jonathan Evans
Parliamentary Under Secretary of State,

Scottish Office
12th August 1996

Lindsay
Parliamentary Under Secretary of State,

Ministry of Agriculture,
Fisheries and Food
7th August 1996

Tony Baldry
Minister of State,

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland
this 15th day of August 1996

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 20th day
of August 1996

L.S.

J. Murray
Permanent Secretary

We consent,

12th August 1996

Bowen Wells
Simon Burns
Two of the Lords Commissioners of Her
Majesty's Treasury

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Animal Use — Fees) Regulations 1995 so as to alter the fees payable in connection with the grant, variation and renewal of animal test certificates, consequent on the Animal Test Certificates Regulations 1996.

Two new fees, of £600 and £250, are set for different types of application for the grant of a certificate (regulations 4 and 5). Formerly there was a single fee of £4,400. A new fee of £200 is set for applications for the variation of certificates (regulation 6). Formerly there was a range of fees from £110 to £1,150. A new renewal fee of £90 is set (formerly the fee was £525) (regulation 7). A consequential amendment is also made (regulation 3). These Regulations do not apply to applications made before their coming into force (regulation 8).

A Compliance Cost Assessment has been prepared and a copy has been placed in the library of each House of Parliament and copies can be obtained from the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3NB.