STATUTORY INSTRUMENTS

1991 No. 632

MEDICINES

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

Made - - - - 12th March 1991
Laid before Parliament 13th March 1991
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THE MEDICINES (FEES RELATING TO MEDICINAL PRODUCTS FOR ANIMAL USE) REGULATIONS 1991

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SCHEDULE 1 — CAPITAL FEES FOR APPLICATIONS, VARIATIONS AND RENEWALS OF LICENCES

PART I — INTERPRETATION

PART II — CAPITAL FEES FOR APPLICATIONS FOR LICENCES AND CERTIFICATES

- 1. Product licences
- 2. Where—(a) a major or a complex application is made...

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- 3. (1) Subject to sub-paragraphs (2) and (3), where an application...
- 4. Animal test certificates
- 5. Manufacturers' licences
- 6. Wholesale dealers' licences
- 7. Animal test (confirmation of exemption) certificate

PART III — FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

- 1. Product licences
- 2. Manufacturers' licences
- 3. Wholesale dealers' licences
- 4. Animal test certificates
- 5. Other variations

PART IV — FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES

- 1. Product licences
- 2. Manufacturers' licences
- 3. Wholesale dealers' licences
- 4. Animal test certificates

SCHEDULE 2 — FEES FOR INSPECTIONS

- 1. Interpretation
- 2. Fees
- 3. (1) Subject to paragraph (2), unless the applicant or, as...
- 4. In the case of an inspection in connection with the...
- 5. The fee payable in respect of any inspection of the...
- 6. The fee payable in respect of an inspection at a...

SCHEDULE 3 — WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

- 1. Where the manufacture, assembly, sale or supply of medicinal products...
- 2. The licensing authority may waive or reduce the payment of...
- 3. (1) Subject to sub-paragraphs (2) to (5), where the licensing...
- 4. Where an application for the grant or renewal of a...
- 5. (1) Subject to sub-paragraph (2), where an application for a...

SCHEDULE 4 — ANNUAL FEES FOR PRODUCT LICENCES PART I — CALCULATION OF TURNOVER

- 1. In relation to the calculation of turnover in any calendar...
- 2. Where a licence holder sells or supplies medicinal products which...
- 3. (1) For the purpose of calculating annual fees for product...
- 4. For the purpose of calculating annual fees for product licences...
- 5. Where the licence holder fails to furnish evidence of the...
- 6. Where an applicant for a licence was not dealing in...

PART II — CALCULATION OF ANNUAL FEES

- 1. Subject to the provisions of these Regulations annual fees shall...
- 2. For the purpose of calculating annual turnover the provisions of...
- 3. The amount payable by way of annual fees in accordance...
- 4. Where in any licence year the licence holder does not...
- 5. Where the holder of, or an applicant for a product...

PART III — LESSER AMOUNTS OF FEES

SCHEDULE 5 — ADJUSTMENT OR REFUND OF ANNUAL FEES

- 1. Where an annual fee has been paid in accordance with...
- 2. Any sums payable to an applicant by way of refund...

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SCHEDULE 6 — FEES FOR REFERENCES TO THE VETERINARY PRODUCTS COMMITTEE OR TO THE MEDICINES COMMISSION

Explanatory Note