STATUTORY INSTRUMENTS

1989 No. 583

MEDICINES

The Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1989

Made - - - - 30th March 1989
Laid before Parliament 3rd April 1989
Coming into force 24th April 1989

THE MEDICINES (FEES RELATING TO MEDICINAL PRODUCTS FOR ANIMAL USE) REGULATIONS 1989

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13. (1) Subject to paragraph (4) and to regulations 22 and...

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

PART I — interpretation

- 1. In this Schedule—"active ingredient" means the ingredient of a...
 PART II capital fees for applications for licences
- 1. Product Licences
- 2. Where a major or a complex application is made by...
- 3. (1) Subject to sub-paragraphs (2) and (3), where an application...
- 4. Manufacturers' Licences
- 5. Wholesale Dealers' Licences

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- PART III capital fees for sample testing in connection with applications for licences
- PART IV fees for applications for variations of licences or certificates
- 1. Product Licences
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- 4. Other Variations
 - PART V fees for applications for renewals of licences
- 1. Product Licences
- 2. Manufacturers' Licences
- 3. Wholesale Dealers' Licences
- 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 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. For the purpose of calculating annual fees for product licences...
- 4. (a) For the purpose of satisfying the Licensing Authority for...
- 5. 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 an application is made by an applicant who was...
- 5. Where a licence holder has duly paid an annual fee...
- 6. Where applications are made on more than one occasion in...
- 7. Where in any licence year the licence holder does not...
- 8. Where the holder of, or an applicant for a product...

PART III — lesser amounts of fees

- 1. Where the holder of a product licence sells or supplies...
- 2. For the purposes of paragraph 1, "emergency vaccines" means (a)...

SCHEDULE 5 — ADJUSTMENT OR REFUND OF ANNUAL FEES

- 1. Where an annual fee has been paid in accordance with...
- 2. Where, after payment of any annual fee payable in accordance...
- 3. In addition to the refunds (if any) payable under the...
- 4. Where, after the payment of the whole or part of...
- 5. Any sums payable to an applicant by way of refund...

SCHEDULE 6 — REVOCATIONS

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Explanatory Note