
STATUTORY INSTRUMENTS

1998 No. 2428

MEDICINES

**The Medicines (Products for Animal
Use—Fees) Regulations 1998**

Made - - - - 29th September 1998

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Coming into force 1st November 1998

**THE MEDICINES (PRODUCTS FOR
ANIMAL USE—FEES) REGULATIONS 1998**

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14. Registration of Homoeopathic Veterinary Medicinal Products
15. Marketing authorisations, product licences and animal test certificates: fees for references to the Veterinary Products Committee or to the Medicines Commission
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18. Late payment of annual fees
 19. Suspension of licences and certificates
 20. Waiver, reduction or refund of fees
 21. Revocation
 22. Transitional provisions
- Signature

SCHEDULE 1 — FEES RELATING TO APPLICATIONS FOR THE GRANT, VARIATION AND RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

PART I — INTERPRETATION

— PART II FEES RELATING TO APPLICATIONS FOR THE GRANT OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

1. Marketing authorisations and product licences
2. The fee for an application for an Article 15.2 marketing...
3. Where an application for a marketing authorisation is made by...
4. Where— (a) a major or a complex application is made...
5. (1) Subject to sub-paragraphs (2), (3) and (4) below, where...
6. Manufacturer's licences
7. Wholesale dealer's licences
8. Animal test certificates
9. Marketing authorisation (parallel import)

PART III — FEES RELATING TO APPLICATIONS FOR ASSISTANCE IN CONNECTION WITH MUTUAL RECOGNITION APPLICATIONS

1. Subject to paragraphs 3 and 4, where an application for...
2. Where an application for assistance in connection with a mutual...
3. Where an application for assistance in connection with a mutual...
4. Where an application for assistance in connection with a mutual...
5. (1) Where an application for assistance in connection with a...

PART IV — FEES RELATING TO APPLICATIONS FOR THE VARIATION OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

1. Marketing authorisations (other than mutually recognised marketing authorisations) and product licences
2. The fee for an application of a kind described in...
3. Mutually recognised marketing authorisations
4. The fee for an application for a connected variation, that...
5. Manufacturer's licences
6. Wholesale dealer's licences
7. Animal test certificates

PART V — FEES RELATING TO APPLICATIONS FOR THE RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES AND ANIMAL TEST CERTIFICATES

1. Marketing authorisations and product licences
2. Manufacturer's licences
3. Animal test certificates
4. Article 15.2 marketing authorisations

SCHEDULE 2 — FEES RELATING TO SITE INSPECTIONS

1. Interpretation
2. Fees
3. (1) The fee payable for any inspection of either or...
4. (1) The fee payable for an inspection at a site...

SCHEDULE 3 — MARKETING AUTHORISATIONS AND PRODUCT LICENCES: ANNUAL FEES

PART I

1. Calculation of turnover
2. To the extent that a marketing authorisation or product licence...
3. For the purpose of calculating any annual fee payable in...
4. (1) The relevant authority may require a marketing authorisation or...

PART II — CALCULATION OF ANNUAL FEES

1. In the case of a business with a turnover of...
2. In the case of a business with a turnover of...
3. For the purpose of calculating annual turnover the provisions of...
4. The amount payable by way of an annual fee in...
5. If a marketing authorisation or product licence holder does not...

PART III — CALCULATION OF ANNUAL FEE—EMERGENCY VACCINES

SCHEDULE 4 — MARKETING AUTHORISATIONS AND PRODUCT LICENCES: ADJUSTMENT OR REFUND OF ANNUAL FEES

1. Where an annual fee calculated in accordance with paragraph 5...
2. Any sums payable to an applicant by way of refund...

SCHEDULE 5 — FEES RELATING TO APPLICATIONS FOR REGISTRATION OF HOMOEOPATHIC VETERINARY MEDICINAL PRODUCTS

PART I — INTERPRETATION

PART II — FEES RELATING TO APPLICATIONS FOR REGISTRATION

1. Subject to paragraph 2, the fee for an application of...
2. Where an application for registration relates to a product—

PART III — WAIVER OR REFUND OF FEES

1. Subject to paragraph 2, where an application for registration is...
2. If an application for registration is withdrawn either after veterinary,...

SCHEDULE 6 — MARKETING AUTHORISATIONS, PRODUCT LICENCES AND ANIMAL TEST CERTIFICATES: FEES FOR REFERENCES TO THE VETERINARY PRODUCTS COMMITTEE OR TO THE MEDICINES COMMISSION

1. The fee payable under regulation 15 for a reference to...
2. The fee payable under regulation 15 for a reference to...
3. For the purposes of this Schedule, the terms— “complex application”;...

SCHEDULE 7 — WAIVER, REDUCTION OR REFUND OF FEES

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

Explanatory Note