STATUTORY INSTRUMENTS

## 1989 No. 418

### **MEDICINES**

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

Made	-	-	-	-	
Laid bef	fore F	Parli	amer	nt	
Coming	into	force	2		

9th March 1989 10th March 1989 1st April 1989

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

#### PART I

#### GENERAL

- 1. Citation, commencement and scope
- 2. Interpretation

#### PART II

#### FEES FOR APPLICATIONS FOR LICENCES OR CERTIFICATES AND FOR INSPECTIONS IN CONNECTION THEREWITH

- 3. Applications for Licences
- 4. Applications for Clinical Trial Certificates
- 5. Applications for certificates for exports of medicinal products

#### PART III

#### FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

- 6. Variations of Licences
- 7. Variations of Clinical Trial Certificates
- 8. Change of Name or Address in Clinical Trial Certificates
- 9. Applications for Multiple Variations

**Status:** This is the original version (as it was originally made).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

#### PART IV

#### FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES OR CERTIFICATES

- 10. Renewal of Licences
- 11. Renewal of Certificates
- 12. Renewals in terms which are not identical to the existing licence or certificate

#### PART V

#### FEES FOR INSPECTIONS MADE DURING THE CURRENCY OF A LICENCE

13. (1) Subject to paragraph (4) below and to regulations 16...

#### PART VI

#### ADMINISTRATION

- 14. Payment of fees to Ministers
- 15. Time for payment of fees in connection with applications or inspections and refunds of such fees
- 16. Waiver, Reduction or Refund of Fees
- 17. Suspension of Licences
- 18. Civil proceedings to recover unpaid fees

#### PART VII

#### REVOCATION, SAVINGS AND TRANSITIONAL PROVISIONS

- 19. Revocation and Savings
- 20. Transitional provisions Signature
  - Signature

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

#### PART I — INTERPRETATION

- 1. In this Schedule "active ingredient" means the ingredient of... PART II — FEES FOR APPLICATIONS FOR LICENCES
- 1. Product Licences
- 2. Where a major application is made by a person who...
- 3. (1) Subject to sub-paragraphs (2) and (3) below, where an...
- 4. Manufacturers' Licences
- 5. Wholesale Dealers' Licences
  - PART III FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES
- 1. Product Licences
- 2. Manufacturers' Licences
- 3. Wholesale Dealers' Licences
- 4. Other Variations

1.

- 2. Manufacturers' Licences
- 3. Wholesale Dealers' Licences

PART IV — FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES Product Licences

#### SCHEDULE 2 — FEES FOR INSPECTIONS

- 1. Interpretation
- 2. Fees
- 3. (1) Subject to sub-paragraph (2) below, unless the applicant or,...
- 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 FEES

- 1. Where the manufacture, assembly, sale or supply of medicinal products...
- 2. (1) Subject to sub-paragraph (2) below, where an application for...
- 3. Where an application for a manufacturer's or a wholesale dealer's...
- 4. Where the same site is inspected at the same time...

#### SCHEDULE 4 — REGULATIONS REVOKED IN SO FAR AS THEY APPLY IN RELATION WHOLLY OR PARTLY TO MEDICINAL PRODUCTS FOR HUMAN USE

The Medicines (Fees) Regulations 1978 The Medicines (Fees) Amendment Regulations...

Explanatory Note