
STATUTORY INSTRUMENTS

1991 No. 632

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

PART III

FEEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES AND FOR INSPECTIONS IN CONNECTION THEREWITH

Variations of licences and certificates

5. Subject to regulations 6, 7, 19 and 21, in connection with an application under section 30 of the Act for the variation of a provision of a product licence, a manufacturer's licence or a wholesale dealer's licence, under section 39(4) In respect of an animal test certificate or an animal test (confirmation of exemption) certificate there shall be payable by the applicant—

- (a) the fee prescribed in Part III of Schedule 1; and
- (b) in respect of any inspection of a description referred to in paragraphs 1 or 5 of Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2, 3, 4 and 6 of that Schedule.

Applications for multiple variations

6. A separate fee shall be payable in respect of each variation of each provision of a licence or certificate applied for in any one application except that no separate fee shall be payable in respect of any variation which is related to or is consequential upon another variation of a provision of the same licence or certificate which is applied for in the same application.

Variations at the invitation of the licensing authority

7. Where an application for a variation is made at the express written invitation of the licensing authority, no fee shall be payable under this Part of these Regulations.