#### STATUTORY INSTRUMENTS

# 1991 No. 632

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

## PART V

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

### Inspections of a site

- 10.—(1) Subject to paragraph (4) and to regulations 19 and 21, a fee in accordance with paragraphs 2, 3, 4 and 6 of Schedule 2 shall be payable in respect of any inspection of a site made during the currency of a product licence, a manufacturer's licence or a wholesale dealer's licence (except for any inspection in respect of which a fee is otherwise payable under Parts III or IV of these Regulations).
- (2) The fee payable under paragraph (1) in respect of an inspection of a site made during the currency of a manufacturer's licence or a wholesale dealer's licence shall be payable by the holder of the manufacturer's licence or, as the case may be, the wholesale dealer's licence.
- (3) Where a fee is payable under paragraph (1) in respect of an inspection of a site located outside the United Kingdom, the fee shall be payable in equal proportions by each holder of a product licence in which that site is named as a possible site for manufacture of the medicinal product in respect of which the product licence is granted.
- (4) No fee shall be payable in respect of any inspection of a site carried out within 6 months of a previous inspection in order to ascertain whether alterations or improvements to the premises concerned, which were required in writing by the licensing authority as the result of that previous inspection, have been implemented.