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STATUTORY INSTRUMENTS

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**1995 No. 1116**

**The Medicines (Products for Human  
Use — Fees) Regulations 1995**

**PART V**

**FEEES FOR INSPECTIONS MADE DURING THE CURRENCY  
OF A MARKETING AUTHORIZATION OR LICENCE**

**Fees for inspections**

**13.**—(1) Subject to paragraph (5) and to regulations 19 and 23, a fee in accordance with paragraphs 2 to 6 of Schedule 2 shall be payable in respect of any inspection of a site made during the currency of a marketing authorization, 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) Subject to paragraph (4), 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 that licence.

(3) Where an inspection is made at a site located outside the United Kingdom and that site is named in more than one marketing authorization as a possible site for the manufacture of the medicinal product in respect of which the authorization is granted the fee payable under paragraph (1) shall be payable in equal proportions by each holder of a marketing authorization in which that site is named as a possible site for manufacture of the medicinal product in respect of which the marketing authorization is granted.

(4) Where an inspection is made at a site located in the United Kingdom and that site is named in more than one manufacturer's licence as a possible site for the manufacture of a medicinal product in respect of which the licence is granted the fee payable under paragraph (1) shall be payable in equal proportions by the holders of those licences.

(5) 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 carried out.