

## SCHEDULE 3

Regulations 11(1) and 18(3)

### MARKETING AUTHORISATIONS AND PRODUCT LICENCES: ANNUAL FEES

#### PART I

##### Calculation of turnover

1. In relation to the calculation of turnover in products of any marketing authorisation or product licence holder in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule, “manufacturers' prices” shall mean, subject to the provisions of paragraph 2, the prices charged for the products by manufacturers to wholesalers, except to the extent that the products are supplied by manufacturers direct to retailers, in which case it shall mean the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the relevant authority, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products.

2. To the extent that a marketing authorisation or product licence holder sells or supplies products which he has neither manufactured nor obtained from the manufacturer, in relation to the calculation of turnover in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule “manufacturers' prices” shall mean the prices paid by, or on behalf of, the marketing authorisation or product licence holder for those products.

3. For the purpose of calculating any annual fee payable in respect of marketing authorisations and product licences, “turnover” means the gross value at manufacturers' prices of all authorised or licensed products sold or supplied in the United Kingdom during the previous calendar year and in relation to which the person from whom the fee is due holds the marketing authorisation or product licence.

4.—(1) The relevant authority may require a marketing authorisation or product licence holder to furnish an auditor's certificate containing evidence of the amount of the holder's annual turnover.

(2) If within one month of the date by which such certificate is required to be furnished, or such longer period as the relevant authority may allow, the marketing authorisation or product licence holder has failed to furnish such certificate the sum payable by way of fees for the period in question shall be calculated as provided for in paragraph 5 of Part II of this Schedule or shall be such lesser sum, based on the relevant authority's estimate of turnover, as the relevant authority shall specify in a notice served on the marketing authorisation or product licence holder.

#### PART II

##### CALCULATION OF ANNUAL FEES

1. In the case of a business with a turnover of £2,800,000 or over, the fee payable shall, subject to paragraph 4 and Part III of this Schedule, be £248 for each marketing authorisation or product licence held, plus £17,640 plus 0.42% of annual turnover in excess of £2,800,000.

2. In the case of a business with a turnover of less than £2,800,000, the fee payable shall, subject to paragraph 4 and Part III of this Schedule, be £205 or 0.63% of annual turnover, whichever is the greater, except that a business with no turnover shall be exempt from any annual fee.

3. For the purpose of calculating annual turnover the provisions of Part I of this Schedule shall apply.

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4. The amount payable by way of an annual fee in accordance with this Schedule shall, if it includes or comprises a fee charged on a percentage basis, as the result of the application of paragraph 1 or 2, be rounded up to the nearest £10.

5. If a marketing authorisation or product licence holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the relevant authority, the annual fee payable by him for that year shall be the sum of £10,000 together with an additional £2,000 for each description of product in respect of which a marketing authorisation or product licence is held by the authorisation or licence holder.

### **PART III**

#### **CALCULATION OF ANNUAL FEE—EMERGENCY VACCINES**

To the extent that the holder of a marketing authorisation or product licence sells or supplies emergency vaccines, the annual fee payable shall be 0.63% of turnover, calculated in accordance with the provisions of Part I of this Schedule rounded up to the nearest £1, except that the minimum sum payable under this provision shall be £10.