

SCHEDULE 3

PERIODIC FEES FOR LICENCES

PART 2

Calculation of Turnover

Calculation of turnover

2.—(1) Subject to sub-paragraph (2), “turnover” means, for the purposes of calculating the periodic fee payable in connection with the holding of a marketing authorization for a relevant fee period, the gross value at manufacturer’s prices of all medicinal products to which the authorization relates which are sold or supplied in the United Kingdom by the holder of the authorization during the period of 12 months preceding the commencement of the relevant fee period.

(2) For the purposes of calculating the periodic fee payable in connection with the holding of marketing authorizations mentioned in Part 4 of this Schedule for a relevant fee period, the quantity of products taken for the purposes of sub-paragraph (1) is the aggregate of all the products to which the authorizations relate.

Manufacturer’s prices

3. For the purposes of paragraph 2, manufacturer’s prices are the following—

- (a) for products sold or supplied by the authorization holder to wholesalers or to distributors or assemblers named in the marketing authorization, which that holder has manufactured or obtained from the manufacturer, the prices charged for the supply;
- (b) for products sold or supplied by the authorization holder to retailers, which that holder has manufactured or obtained from the manufacturer, the prices so charged for the supply less an amount which, in the opinion of the licensing authority, represents the difference between those prices and the prices which would have been charged, in accordance with the practice prevailing during the relevant year, by a wholesaler for the product; or
- (c) for products sold or supplied by the authorization holder which that holder has neither manufactured nor obtained from the manufacturer, the price which he paid for the supply.

Evidence of turnover

4.—(1) For the purpose of satisfying the licensing authority for the purposes of Part 3 of this Schedule, an applicant shall, if requested, state the amount of the turnover, calculated in accordance with paragraphs 2 and 3.

(2) Where the authorization holder fails to furnish evidence of the amount of annual turnover to the satisfaction of the licensing authority, the licensing authority may require the authorization holder to furnish an auditor’s certificate containing such evidence.

(3) If within one month of the date by which such certificate is required to be furnished, or such longer period as the licensing authority may allow, the authorization holder has failed to furnish such certificate, the sum payable by way of periodic fees for the relevant fee period in question shall be equal to the fee provided for in paragraphs 10 and 13 of Part 3 of this Schedule or shall be such lesser sum as the licensing authority may specify in a written notice served on the authorization holder.