
STATUTORY INSTRUMENTS

2010 No. 551

The Medicines (Products for Human
Use) (Fees) Regulations 2010

PART 7

Capital Fees for Applications for Renewals of Certain Licences,
Authorizations and Registrations and for Associated Inspections

Fees for renewals of certain manufacturer's licences

24.—(1) The fee payable by the applicant for an application to renew a manufacturer's licence which falls within the description in paragraph (2) is £174.

(2) The licence referred to in paragraph (1) is one—

- (a) which is solely for the manufacture of medicinal products the sale or supply of which does not require a marketing authorization or a product licence; and
- (b) to which article 2(2)(i)(e) (exemptions for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(1) applies.

(3) Where an inspection of a site is made in connection with the application referred to in paragraph (1) an inspection fee of £287 is also payable by the applicant.

Fees for renewals in terms which are not identical to the existing authorization, licence or registration

25. Where an applicant applies for renewal of a—

- (a) marketing authorization (other than a European Union marketing authorization);
- (b) traditional herbal registration;
- (c) manufacturer's licence; or
- (d) wholesale dealer's licence,

so as to contain provisions which are not identical to those in the authorization, registration or licence as in force at the date of the application, the fee payable under this Part is increased by an amount equal to the fee which would have been payable under Part 5 of these Regulations had the applicant made a separate application for variation of that authorization, registration or licence in respect of each provision which is not identical.