
STATUTORY INSTRUMENTS

1995 No. 1116

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

PART II

**CAPITAL FEES FOR APPLICATIONS FOR AUTHORIZATIONS,
LICENCES OR CERTIFICATES AND FOR ASSOCIATED INSPECTIONS**

Applications for authorizations, licences or certificates

4. Subject to regulations 5, 19 and 23, in connection with an application for a marketing authorization (other than a Community marketing authorization), a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate, there shall be payable by the applicant—

- (a) the fee prescribed in Part II of Schedule 1 in connection with that application; and
- (b) in respect of any inspection defined in paragraph 1 of Schedule 2 made in connection with that application the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

Inspections in connection with multiple applications for authorizations or licences

5. Where an inspection mentioned in regulation 4(b) is made at a site which has been named as a possible site for manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product, by more than one applicant for—

- (a) a marketing authorization and that site is located outside the United Kingdom; or
- (b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each of those applicants.

Applications for certificates by exporters of medicinal products

6.—(1) In connection with an application for a certificate issued under section 50 (export certificates) of the Act, there shall be payable by the applicant—

- (a) if the applicant requests that the certificate be issued within 24 hours of receipt of the application, a fee of £120;
- (b) in any other case, a fee of £60; and
- (c) in either case
 - (i) a fee of £60 for each set of certificates requested by the applicant in addition to one: and
 - (ii) a fee of £14 for each certified copy of the original certificate not forming part of a set of certificates, requested by the applicant.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- (2) In paragraph (1)(c), “set of certificates” means—
- (a) if it is the first set, the original certificate plus up to four certified copies of that certificate;
and
 - (b) in any other case, up to five copies of that certificate.