STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

The Medicines (Products for Human Use) (Fees) Regulations 2012

PART 3

Capital Fees for Applications for Authorizations, Registrations, Licences, Certificates or Authorisations and for Associated Inspections

Fees for applications for authorizations, licences or certificates etc.

12.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the application fee for a marketing authorization (other than a European Union marketing authorization), a traditional herbal registration, a manufacturer's licence, a manufacturing authorisation, a wholesale dealer's licence or a clinical trial authorisation is—

(a) the fee prescribed for that application in Part 2 of Schedule 2; and

(b) in respect of an inspection of a site made in connection with that application, the fee payable in accordance with regulations 27 to 32.

(2) Unless regulation 28 applies, the fee in paragraph (1) is payable by the applicant.

Fee for applications for copy certificates of good manufacturing practice

13. The fee payable by an applicant for a certified copy of a certificate of good manufacturing practice issued pursuant to Article 111(5) of the 2001 Directive is £67.

Fees for applications for certificates and copy certificates by exporters of medicinal products

14.—(1) The fee payable by an applicant for a certificate issued under section 50 (export certificates) of the Act(**1**), is—

(a) £148, if the applicant requests the certificate to be issued within 24 hours of receipt of the application; and

(b) £67 in any other case.

(2) The fee in paragraph (1)(a) and (b) is for three identical signed certificates.

(3) The fee payable by the applicant for a certified copy of the certificate referred to in paragraph (1) is £33.

(**1**) Section 50 has been amended by S.I. 2004/1031.