STATUTORY INSTRUMENTS

2012 No. 504

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

PART 13

Fees in relation to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

Interpretation

39.—(1) In this Part—

"administrative variation" means a variation of the provisions of a certificate of registration which does not require, in the opinion of the licensing authority, medical, scientific or pharmaceutical assessment;

"application" means an application for the grant of a certificate of registration;

"application to the licensing authority for regulatory assistance" in relation to a single certificate of registration means—

(a) a single application of that type, or

(b) a set of applications of that type;

"application for an EC registration in a concerned Member State" in relation to a single certificate of registration means—

(a) a single application of that type, or

(b) a set of applications of that type in a number of concerned Member States;

"decentralised procedure application" means an application relating to a homoeopathic medicinal product in respect of which at the time of the application—

(a) an EC registration has been granted in an EEA State; and

(b) an application for an EC registration has been made in more than one EEA State under Article 28(1) and (3) of the 2001 Directive;

"EC registration" means a registration granted by a competent authority of an EEA State in accordance with the procedure set out in Article 14 of the 2001 Directive;

"formulation" does not include the formulation of homoeopathic stock;

"identical" means—

(a) in relation to the formulation of the product, identical as regards the requirements in respect of composition, preparation and testing; and

(b) in relation to a homoeopathic stock, identical as regards the source, composition and preparation of the stock and the test which it is required to undergo;

"mutual recognition procedure incoming application" means an application relating to a homoeopathic medicinal product in respect of which—

(a) an EC registration has already been granted in another EEA State; and

(b) recognition of that certificate is sought from the licensing authority by way of the grant of a certificate of registration in the United Kingdom, under the procedure in Articles 28 and 29(1) to (3) of the 2001 Directive;

"product" includes a series of products each of which is prepared from identical homoeopathic stocks;

"set of applications" means—

(a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in other EEA States, where those applications to the licensing authority all relate to applications for EC certificates of registration in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or

(b) a number of applications to competent authorities of other EEA States for EC certificates of registration relating to a single certificate of registration, where those applications all have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; and

"standard variation" means a variation of the provisions of a certificate of registration which, in the opinion of the licensing authority, requires medical, scientific or pharmaceutical assessment and which requires in respect of any homoeopathic medicinal products to which that certificate relates—

(a) the replacement of an excipient used in the manufacture of the product with a comparable excipient;

(b) the replacement of a reagent indirectly associated with the manufacturing process of the product or which disappears from that process with a comparable reagent;

(c) a change to the qualitative composition of the container or other form of packaging immediately in contact with the product;

(d) a minor change to the method of manufacture of a homoeopathic stock included in the product;

(e) a change to the specification of any reagent or excipient used in the manufacture of the product;

(f) a change to the finished product specification of the product;

(g) a change to the test procedure for any raw material used in the manufacture of the product;

(h) a change to the test procedure of the product;

(i) a change to the test procedure for the container or other form of packaging immediately in contact with the product;

(j) a change to comply with a supplement to the European Pharmacopoeia or any national pharmacopoeia of a member State;

(k) a change to the shape of the container in which the product may be placed on the market;

(l) an additional pack size in which the product may be placed on the market;

(m) a change to the approved storage conditions for the product;

(n) a change to the shelf life of an unopened container of the product or to the shelf life of the product after the container has been opened for the first time;

(o) a change to the dimensions of an approved dosage form of the product (for example, tablets) which does not entail a change to the quantitative composition or the mean mass of the product; or

(p) a change following modification to the manufacturing authorisation.

(2) In this Part—

(a) any expression which is defined in the Act shall have the same meaning which it has in the Act;

(b) any expressions which are also used in the 2001 Directive shall have the same meaning as they have in the 2001 Directive and related expressions shall be interpreted accordingly;

(c) any reference to doing anything in accordance with a certificate of registration shall be interpreted in accordance with section 132(3) of the Act (general interpretation provisions); and

(d) any reference to the holder of a certificate of registration shall be interpreted as a reference to the holder of such a certificate which is for the time being in force.

Fees for applications made at the invitation of the licensing authority

40. No fee shall be payable under this Part in connection with an application for the grant or variation of a certificate of registration under the Homoeopathic Regulations where the application is made at the specific request of the licensing authority.

Fees for applications for certificates

41.—(1) The fee payable by a person who makes an application for the grant of a certificate of registration under regulation 4 of the Homoeopathic Regulations shall be the fee specified in the Table in Schedule 5 to these Regulations according to the type of application.

(2) The fee payable by a person who makes an application or set of applications to the licensing authority for regulatory assistance in connection with obtaining recognition in accordance with the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in another EEA State, shall be the fee specified in item 4 of the Table in Schedule 5 to these Regulations.

Fees for variations of certificates

42.—(1) The fee payable by an applicant in connection with an application for an administrative variation of a certificate of registration shall be—

(a) where more than one application for an administrative variation is made at the same time by the same applicant and the applications are for identical variations—

(i) in respect of the first application considered by the licensing authority, a fee of £133, and

(ii) in respect of each other application so considered, a fee of £67;

(b) in any other case, a fee of £133.

(2) The fee payable by an applicant in connection with an application for a standard variation of a certificate of registration shall be—

(a) where more than one application for a standard variation is made at the same time by the same applicant and the applications are for identical variations—

(i) in respect of the first application considered by the licensing authority, a fee of £263;

(ii) in respect of each other application so considered, where further medical, technical or scientific assessment is required, a fee of £263;

(iii) in respect of the second to thirtieth applications so considered, where no further medical, technical or scientific assessment is required, a fee of £133;

(iv) in respect of each other application so considered, where no further medical, technical or scientific assessment is required, a fee of £67;

(b) in any other case, a fee of £263.

Time for payment of fees

43.—(1) Any fee payable under regulation 41(1) or 42 shall be payable to the licensing authority—

(a) in advance of the application; or

(b) at the time the application for grant or variation of the certificate of registration is made.

(2) Any fee payable under regulation 41(2) shall be payable to the licensing authority—

(a) in advance of any request; or

(b) at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under Article 28(2) of the 2001 Directive for an assessment report to be prepared or updated.