STATUTORY INSTRUMENTS

2012 No. 504

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

PART 5

Capital Fees for Applications for Variations of Authorizations, Registrations, Licences and Authorisations and for Associated Inspections

Fees for variations of authorizations, registrations, licences and authorisations

18.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the fee for an application—

(a) under regulation 4 (applications for the grant, renewal or variation of a United Kingdom marketing authorization) of the Marketing Authorisation Regulations(**1**) for the variation of a United Kingdom marketing authorization;

(b) under regulation 6 (consideration and grant or refusal, of an application for, or for renewal or variation of, a traditional herbal registration) of the Herbal Regulations for the variation of a traditional herbal registration;

(c) under section 30 (variation of licence on application of holder) of the Act(**2**) for the variation of a product licence, a manufacturer's licence or a wholesale dealer's licence; or

(d) under regulation 44 (variation of manufacturing authorisation) of the Clinical Trials Regulations(**3**) for the variation of a manufacturing authorisation,

is the fee mentioned in paragraph (2).

(2) The fee referred to in paragraph (1) is—

(a) the fee prescribed in Part 4 of Schedule 2 in connection with the application; and

(b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 27 to 29 and 31.

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

Fees for amendments to clinical trial authorisations

19.—(1) A person who sends a valid notice of amendment under regulation 24 (amendments by the sponsor) of the Clinical Trial Regulations(**4**) relating to amendment of the dossier accompanying a request for authorisation in accordance with paragraph 11 of Part 2 of Schedule 3 (request for authorisation) to those Regulations must pay the fees mentioned in paragraph (2).

(2) The fees referred to in paragraph (1) are—

(**1**) Regulation 4 has been amended by S.I. 2001/795, 2002/236, 2005/2759, 2006/1952.
(**2**) Section 30 was substituted by S.I. 2005/2789.
(**3**) Regulation 44 has been amended by S.I. 2006/1928, 2010/551.
(**4**) Regulation 24 has been amended by S.I. 2006/1928, 2010/551.

(a) the fee prescribed in paragraph 44 of Schedule 2 in connection with that amendment; and

(b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 27 to 29 and 31.

Applications for multiple variations

20.—(1) Unless paragraph (3) or (5) applies, a separate fee is payable in respect of each application to vary each term of a marketing authorization.

(2) Unless paragraph (5) applies, a separate fee is payable in respect of each variation of each provision of a traditional herbal registration, manufacturing authorisation or licence applied for in any one application.

(3) A separate fee is not payable for each application to vary a term of a marketing authorization which—

(a) falls within the same type of group application; or

(b) the licensing authority—

(i) in consultation with other Member States concerned, have agreed, in accordance with Article 7(2)(b) of EC Regulation No. 1234/2008, should be subject to the procedure for grouping of variations within the meaning of that Article; and

(ii) have agreed fall, or should be treated as falling, within the same type of group application.

(4) For the purposes of paragraph (3) the reference to a group application means an application which is a—

(a) Minor Variation (Type IB) Group Application;

(b) Major Variation (Type II) Group Application;

(c) Major Variation (Type II) Complex Group Application; or

(d) Major Variation (Type II) Extended Complex Group Application.

(5) A separate fee is not payable for a variation which is wholly consequential upon another variation of a provision of a marketing authorization, traditional herbal registration, manufacturing authorisation or licence which is applied for in the same application.

(6) In a case where a recommendation on the classification of a variation is made in accordance with Article 5 of EC Regulation No. 1234/2008, the fee payable for the application made in respect of that variation shall be the appropriate fee for the classification given to the variation or, as the case may be, the appropriate fee which arises as a consequence of the classification given to the variation.

(7) In this regulation and Part 4 of Schedule 2—

"Major Variation (Type II) Group Application" means an application for several variations to one marketing authorization and—

(a) at least one of the variations is a major variation of type II;

(b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No. 1234/2008;

(c) the variations do not include a variation—

(i) of a kind referred to in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to EC Regulation No. 1234/2008;

(ii) which relates to a change which is referred to in paragraph 23 of Schedule 2 (Type II Complex Variation Application); or

(iii) of a marketing authorization so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2 (Extended Type II Complex Variation Application); and

(d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB;

"Major Variation (Type II) Complex Group Application" means an application for several variations to one marketing authorization and—

(a) at least one of the variations relates to one or more of the changes referred to in paragraph 23 of Schedule 2;

(b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No. 1234/2008;

(c) the variations do not include a variation of—

(i) a kind referred to in paragraph 1 or paragraph 3 of Annex III to EC Regulation No. 1234/2008; or

(ii) a marketing authorization so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2; and

(d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB or one or more major variations of type II;

"Major Variation (Type II) Extended Complex Group Application" means an application for several variations to one marketing authorization and—

(a) at least one of the variations is a variation to a marketing authorization so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2;

(b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No. 1234/2008;

(c) the variations do not include a variation of a kind referred to in paragraph 1 of Annex III to EC Regulation No. 1234/2008; and

(d) the variations may include minor variations of type IA, minor variations of type IB or other major variations of type II or a variation relating to a change referred to in paragraph 23(a), (b) or (c) of Schedule 2;

"major variation of type II" has the meaning given in Article 2(3) of EC Regulation No. 1234/2008;

"Minor Variation (Type IB) Group Application" means an application for several variations to one marketing authorization and—

(a) at least one of the variations is a minor variation of type IB;

(b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No. 1234/2008;

(c) the variations do not include—

(i) a variation of a kind referred to in paragraph 1 or paragraph 2 of Annex III of EC Regulation No. 1234/2008; or

(ii) a major variation of type II; and

(d) the variations may include one or more minor variations of type IA;

"minor variation of type 1A" has the meaning given in Article 2(2) of EC Regulation No. 1234/2008;

"minor variation of type 1B" has the meaning given in Article 2(5) of EC Regulation No. 1234/2008; and

"work sharing" means the work sharing procedure within the meaning of Article 20 of EC Regulation No. 1234/2008.