STATUTORY INSTRUMENTS

2003 No. 625

The Medicines for Human Use and Medical Devices(Fees Amendments) Regulations 2003

Amendment of the General Fees Regulations

4.—(1) The General Fees Regulations are amended as follows.

(2) In regulation 2(1), in the definition of "marketing authorization" after "means" insert ", except in regulation 3A".

(3) After Part I of the General Fees Regulations (general) insert the following Part—

"PART IA

CAPITAL FEES FOR PRE-APPLICATION MEETINGS

3A. In this Part—

"clinical development" means the conduct of studies of a medicinal product in human subjects in order to—

(a) discover or verify the effects of such a product,

(b) identify any adverse reaction to such a product, or

(c) study absorption, distribution, metabolism and excretion of such a product,

with the object of ascertaining the safety or efficacy of that product, in accordance with Part 4 of Annex I to the 2001 Directive(**1**);

"EC marketing authorization" means—

(a) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations,

(b) a marketing authorization granted by the competent authority of an EEA State other than the United Kingdom in accordance with the 2001 Directive, or

(c) a Community marketing authorization;

"quality development" means the chemical, pharmaceutical and biological testing necessary to demonstrate the quality of a relevant medicinal product, in accordance with Part 2 of Annex I to the 2001 Directive;

"scientific advice" means advice in connection with the quality, safety or clinical development for a relevant medicinal product;

"relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply(**2**);

(**1**) See the definition of "the 2001 Directive" in regulation 2(1) as substituted by S.I.2002/236.
(**2**) See Articles 2 and 3 of the Directive.

"safety development" means the toxicological and pharmacological testing necessary to demonstrate the safety of a relevant medicinal product, in accordance with Part 3 of Annex I to the 2001 Directive.

3B. Subject to regulation 19, where the licensing authority holds a meeting with a person for the purpose of providing scientific advice to that person with a view to him making an application for an EC marketing authorization, there shall be payable by that person—

(a) if the advice provided at that meeting consists of advice in connection with—

(i) quality development only, or

(ii) safety development only,

a fee of £1,000;

(b) if the advice provided at that meeting consists of advice in connection with—

(i) quality and safety development, or

(ii) clinical development only,

a fee of £1,330;

(c) if the advice provided at that meeting consists of advice in connection with—

(i) quality and clinical development, or

(ii) safety and clinical development,

a fee of £1,670; and

(d) if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development, a fee of £2,000.

3C. Subject to regulation 19, all sums payable by way of fees under regulation 3B shall become payable within 14 days following written notice from the licensing authority requiring payment of those fees.".

(4) After Part III of the General Fees Regulations (capital fees for applications for variations of authorizations, licences or certificates and for associated inspections) insert the following Part—

"PART IIIA

CAPITAL FEES FOR ASSESSMENT OF LABELS AND LEAFLETS

9A. For the purposes of this Part and Part IIIA of Schedule 1, a "set of proposed changes" means a number of proposed changes to the labelling or package leaflet of a medicinal product, where—

(a) if there is more than one version of the labelling or package leaflet for that product, those changes all relate to the same version; and

(b) those changes are submitted to the licensing authority at the same time.

9B.—(1) Subject to paragraph (2) and regulation 19, where—

(a) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a United Kingdom marketing authorization (other than a parallel import licence) is submitted to the licensing authority in accordance with Article 61(3) of the 2001 Directive, or

(b) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a parallel import licence is submitted to the licensing authority,

there shall be payable by the holder of that authorization or licence the fee prescribed in Part IIIA of Schedule 1 in connection with that change.

(2) Paragraph (1) shall not apply where a change to the labelling or package leaflet of a medicinal product is proposed in connection with an application for the variation of the marketing authorization for that product.

9C. Subject to regulation 19, all sums payable by way of fees under regulation 9B(1) shall be payable at the time when the proposed changes are submitted to the licensing authority.".

(5) In regulation 16 (time for payment of capital fees in connection with applications or inspections), in paragraph (1)—

(a) after "6C" insert "or 9C"; and

(b) after "regulation" insert "3C,".

(6) After Part III of Schedule 1 (capital fees for applications for variations of authorizations, licences and certificates) insert the following Part—

"PART IIIA

CAPITAL FEES FOR ASSESSMENT OF LABELS AND LEAFLETS

1. In this Part, "clinical particulars", in relation to a medicinal product, means the clinical particulars contained in the Summary of Product Characteristics for that product as specified in paragraph 5 of Article 11 of the 2001 Directive.

2. Subject to paragraph 3, the fee payable under regulation 9B(1) in connection with a set of proposed changes to the labelling or the package leaflet of a medicinal product shall be—

(a) in respect of a product which is the subject of a United Kingdom marketing authorization other than a parallel import licence, £350; and

(b) in respect of a product which is the subject of a parallel import licence, £270.

3.—(1) This paragraph applies where more than one set of proposed changes falling within regulation 9B(1) is submitted by the same marketing authorization holder at the same time and where—

(a) the sets of proposed changes consist of identical changes to the labelling or package leaflets of products with the same active ingredient or combination of ingredients, dosage form and clinical particulars; or

(b) the sets of proposed changes consist of identical changes to different versions of the labelling or package leaflet of the same product.

(2) Where this paragraph applies, the fee payable under regulation 9B(1) shall be—

(a) in connection with the first set of proposed changes considered by the licensing authority, the appropriate amount specified in paragraph 2; and

(b) in connection with each of the other sets of proposed changes, 50 per cent of that amount.".

(7) In Schedule 2 (fees for inspections)—

(a) in paragraph 1 (interpretation), in sub-paragraph (1)—

(i) before the definition of "major inspection" insert the following definition—

""exempt imported product" means a medicinal product, as defined in Article 1.2 of the 2001 Directive, to which paragraph 1 of Schedule 1 to the 1994

Regulations applies, which was not manufactured in the United Kingdom and in relation to which no marketing authorization has been granted;", and

(ii) after the definition of "minor inspection" insert the following definitions—

""new premises or facilities", in relation to an inspection at a site, means premises or facilities—

(a) which have not been specified in any application for the grant, variation or renewal of a manufacturer's licence, other than an application to which the inspection relates, or

(b) which have been so specified, provided that—

(i) no manufacturing or assembly operations have been carried out at those premises or facilities, or

(ii) no inspection has been made of those premises or facilities on or after the date on which manufacturing or assembly operations were first carried out at those premises or facilities;

"non-routine inspection" means an inspection at a site in connection with the grant, variation or renewal of a manufacturer's licence or during the currency of such a licence which—

(a) relates to new premises or facilities on that site, or plans for such premises or facilities,

(b) relates to a material alteration of any existing premises or facilities at that site, or plans for such an alteration, provided that if the alteration has been made prior to the inspection—

(i) no manufacturing or assembly operations have been carried out at those premises or facilities since the alteration, or

(ii) no inspection has been made of those premises or facilities on or after the date on which manufacturing or assembly operations were first carried out following that alteration, or

(c) is made to ascertain whether the holder of the licence is able to demonstrate compliance with—

(i) any principle or guideline of good manufacturing practice (but not all those principles and guidelines), or any individual requirement of such a principle or guideline; or

(ii) the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" published by the European Commission in Volume 3 of its publication "The Rules Governing Medicinal Products in the European Union";

"principle or guideline of good manufacturing practice" means one of the principles and guidelines of good manufacturing practice set out in Chapter II of Commission Directive 91/356/EEC(**3**) laying down the principles and guidelines of good manufacturing practice for medicinal products for human use;";

(b) in paragraph 2—

(i) at the beginning of sub-paragraph (b) insert "except in the case of an inspection falling within sub-paragraph (cc)",

(**3**) OJNo. L193, 17.7.91, p. 30.

(ii) in sub-paragraph (c), for "(b) or (d)" substitute "(b), (cc) or (d)",

(iii) after sub-paragraph (c), insert the following paragraph—

"(cc) except in the case of an inspection falling within sub-paragraph (d), where the inspection is a non-routine inspection—

(i) if the time taken to make the inspection is not more than one day, £1,500,

(ii) if the time taken to make the inspection is more than one day but not more than 3 days, £4,000,

(iii) if the time taken to make the inspection is more than 3 days, £7,500; and"; and

(c) in paragraph 3, in sub-paragraph (1), after "any inspection at a site" insert "(other than a non-routine inspection)";

(d) in paragraph 4—

(i) in sub-paragraph (1), for "sub-paragraph (2)" substitute "sub-paragraphs (2) and (3)", and

(ii) after sub-paragraph (2), insert the following sub-paragraph—

"(3) This paragraph shall not apply in respect of a non-routine inspection.";

(e) in paragraph 5—

(i) in sub-paragraph (1), at the beginning insert "Subject to paragraph (3),", and

(ii) after sub-paragraph (2), insert the following sub-paragraph—

"(3) In the case of an inspection of a site in connection with the variation or renewal of a wholesale dealer's licence which relates to exempt imported products or during the currency of such a licence, the fee payable shall be the fee specified in the entry in column 2 of the following Table corresponding to the number of such products imported under that licence in the period of 12 months before the inspection specified in column 1 of that Table—

Column 1 *Number of exempt imported products imported in previous 12 months*	*Column 2* *Fee payable*
None	£1,011
1 to 4	£1,211
5 to 20	£2,011
21 to 100	£4,011
101 to 500	£9,011
More than 500	£16,011"; and

(f) after paragraph 5, insert the following paragraph—

"**5A.** The fee payable in respect of an inspection at a site during the currency of a marketing authorization for the purposes of ascertaining whether the holder of that authorization has complied with the obligations relating to pharmacovigilance imposed on him by virtue of regulation 7(1) and (2) of the 1994 Regulations(**4**) shall be—

(**4**) See the definition of "the 1994 Regulations" in regulation 2(1) of the General Fees Regulations.

(a) if the holder of the marketing authorization holds less than 5 such authorizations, £3,500;

(b) if the holder of the marketing authorization holds 5 or more such authorizations, but less than 50, £5,000; and

(c) if the holder of the marketing authorization holds 50 or more such authorizations, £10,000.".

(8) In Schedule 5 (waiver, reduction or refund of capital fees)—

(a) paragraph 2 is renumbered as sub-paragraph (1) of that paragraph and after that sub-paragraph insert the following sub-paragraph—

"(2) Where, at the specific request of the licensing authority, a proposed change is submitted to the licensing authority as a consequence of new information having a bearing on the safe use of the product, the fee payable under regulation 9B(1) shall be refunded or, if it has not yet been paid, shall be waived."; and

(b) after paragraph 5, insert the following paragraph—

"**5A.** Where the inspection of a site is a non-routine inspection within the meaning of Schedule 2 and the time taken to make that inspection is not more than 2 hours, the fee otherwise payable under these Regulations in respect of that inspection shall be waived.".

(9) In each provision of the General Fees Regulations specified in the entries in column (1) of the Schedule to these Regulations (the content of which is described in column (2) of that Schedule), for the amount specified opposite that provision in column (3) of that Schedule substitute the amount specified opposite that provision in column (4) of that Schedule.