STATUTORY INSTRUMENTS

2008 No. 552

The Medicines (Products for Human Use-Fees) Regulations 2008

PART 2

Capital Fees for Pre-Application Meetings

Interpretation of Part 2

3. 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 section 5 of Part 1 of Annex 1 to the 2001 Directive;

"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;

"pharmacovigilance advice" means advice, other than scientific advice, which falls within one or more of the descriptions specified in paragraphs (a) and (b)—

(a) the advice is in connection with an application for an EC marketing authorization, or is given with a view to a person making such an application, and relates to—

(i) the obligations that would relate to the holder of such an authorization by virtue of Title IX of the 2001 Directive or Chapter 3 of the Title II of Regulation (EC) No. 726/2004,

(ii) the pharmacovigilance and risk-management systems that the applicant would be required to introduce in accordance with Article 8(3)(ia) of the 2001 Directive, or

(iii) a post-authorization safety study protocol;

(b) the advice is given to the holder of a United Kingdom marketing authorization or a Community marketing authorization and relates to—

(i) compliance with the obligations that relate to him by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004,

(ii) the pharmacovigilance and risk-management systems that he has introduced in accordance with Article 8(3)(ia) of the 2001 Directive, or

(iii) a post-authorization safety study protocol;

"post-authorization safety study protocol" means a document that describes the objectives, design, methodology, statistical considerations and organisation of a post-authorization safety study;

"product range" means one or more medicinal products containing the same active substance in relation to which the same person holds more than one EC marketing authorization;

"quality development" means the chemical, pharmaceutical and biological testing necessary to demonstrate the quality of a relevant medicinal product, in accordance with section 3 of Part 1 of Annex 1 to the 2001 Directive;

"regulatory advice" means advice, other than scientific advice, in relation to the requirements of the 2001 Directive or Regulation (EC) No. 726/2004 and which falls within one or more of the descriptions specified in paragraphs (a) to (c)—

(a) the advice is in connection with a change to the dates for renewal of one or more EC marketing authorizations relating to a product range pursuant to Article 24 of the 2001 Directive;

(b) the advice is in connection with—

(i) a referral pursuant to Article 30, 31 or 36 of the 2001 Directive, or

(ii) the procedure referred to in Article 35(2) of the 2001 Directive,

in relation to a product range; or

(c) the advice is given to a person with a view to him making—

(i) an application for the variation or renewal of one or more EC marketing authorizations, or

(ii) an application to amend the time periods for submitting Periodic Safety Update Reports under Article 104(6) of the 2001 Directive,

in relation to a product range;

"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; and

"safety development" means the toxicological and pharmacological testing necessary to demonstrate the safety of a relevant medicinal product, in accordance with section 4 of Part 1 of Annex 1 to the 2001 Directive.

Fee for scientific advice: application for or variation to EC marketing authorization

4. Unless regulation 5 or 44 apply, the fee payable by a person with whom the licensing authority holds a meeting in order to provide scientific advice with a view to that person making an application for an EC marketing authorization or an application for the variation of a marketing authorization, is—

(a) £2,227, if the advice provided at that meeting consists of advice in connection with—

(i) quality development only, or

(ii) safety development only;

(b) £2,797, if the advice provided at that meeting consists only of advice in connection with clinical development;

(c) £3,099, if the advice provided at that meeting consists only of advice in connection with quality and safety development;

(d) £3,669, if the advice provided at that meeting consists of advice in connection with—

(i) quality and clinical development, or

(ii) safety and clinical development;

(e) £4,542, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

Fee for scientific advice: classification of a medicinal product

5.—(1) Unless regulation 44 applies, the fee payable by a person with whom the licensing authority holds a meeting to provide scientific advice in connection with the classification of a relevant medicinal product, is —

(a) £2,797, if the advice relates to a product which if reclassified will be available on general sale; and

(b) £3,699, if the advice relates to a product which if reclassified will be available without a prescription from a pharmacy.

(2) For the purposes of this regulation a product is on general sale if it is a medicinal product of a description, or falling within a class specified in an order made under section 51 (general sale lists) of the Act(**1**).

Fee for advertising advice

6. Unless regulation 44 applies, the fee payable by the holder of a marketing authorization with whom the licensing authority holds a meeting in order to provide advice before the publication of advertising of a medicinal product by his undertaking on whether that advertising conforms to the requirements of Title VIII of the 2001 Directive, is £2,227.

Fee for pharmacovigilance advice

7.—(1) Unless regulation 44 applies, the fee payable by a person with whom the licensing authority holds a meeting in order to provide pharmacovigilance advice is —

(a) £3,699, in a case where the time taken by the licensing authority to prepare for and attend the meeting is more than six hours;

(b) £3,099, in any other case.

(2) The time taken by the licensing authority for the purposes of paragraph (1) shall be the aggregate of times spent by each individual engaged in preparing for or attending the meeting on behalf of the authority.

Fee for advice on labelling or leaflets

8. Unless regulation 44 applies, the fee payable by the holder of one or more marketing authorizations with whom the licensing authority holds a meeting in order to provide advice on proposed changes to the labelling or the package leaflets of the medicinal products to which those authorizations relate, is £2,227.

(**1**) Amendments have been made to section 51 by S.I. 2006/2407.

Fee for regulatory advice

9. Unless regulation 44 applies, the fee payable by the holder of a marketing authorization with whom the licensing authority holds a meeting in order to provide regulatory advice to that person, is £2,797.

Fee for advice for other purposes

10.—(1) Unless regulation 44 applies, the fee payable by a person specified in paragraph (2) with whom the licensing authority holds a meeting for a purpose specified in paragraph (3) is £4,579.

(2) A person who—

(a) is or is to be a sponsor of a clinical trial;

(b) manufactures medicinal products;

(c) is or is to be responsible for placing medicinal products on the market; or

(d) acts on behalf of, or provides advice or assistance to, a person referred to in sub-paragraphs (a) to (c),

is a specified person for the purpose of paragraph (1).

(3) A meeting referred to in paragraph (1) is for a specified purpose if it is held to provide advice in relation to—

(a) scientific or regulatory issues relating to the development of a medicinal product or a type of medicinal product;

(b) the design of pharmaceutical or pre-clinical tests, or clinical trials, for a medicinal product or a type of medicinal product;

(c) the management of risk in relation to a medicinal product or a type of medicinal product which is under development, or is being marketed in the European Community; or

(d) other scientific or regulatory issues relating to a medicinal product or a type of medicinal product after an EC marketing authorization has been granted for that product or a product of that type.

(4) This regulation does not apply to a meeting for the purpose of providing only any advice specified in regulations 4 to 9.

(5) In this regulation—

"medical device" has the same meaning as in Article 1(2)(a) of Directive 93/42/EEC;

"Directive 93/42/EEC" means Council Directive 93/42/EEC concerning medical devices (**2**);

"medicinal product" includes a substance incorporated in a medical device which, if used separately, may be considered to be a medicinal product as defined in Article 1(2) of the 2001 Directive;

"regulatory issues" means issues relating to the application of any Community instrument relating to EC marketing authorizations or to medical devices, or any enactment which implements such an instrument;

"risks" means any risk relating to the quality, safety or efficacy of a medicinal product as regards patients' health or public health, or any risk of undesirable effects on the environment;

"sponsor" shall be construed in accordance with regulation 3 (sponsor of a clinical trial) of the Clinical Trials Regulations(**3**);

(**2**) OJNo. L 169, 12.7.93, p.1. This Directive has been amended by Directive 2000/70/EC of the European Parliament and of the Council (OJ No. L313, 13.2.2000, p.22), Directive 2001/104/EC of the European Parliament and of the Council (OJ No. L6, 10.1.2002, p.50) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No. L 247, 21.9.2007, p.21).
(**3**) Regulation 3 has been amended by S.I. 2006/1928.

and a reference to the development of a medicinal product or a type of medicinal product is a reference to development for the purposes of—

(a) obtaining an EC marketing authorization, or making a variation to an EC marketing authorization, for that product or a product of that type, or

(b) obtaining an EC design-examination certificate within the meaning of paragraph 4.3 of Annex II to Directive 93/42/EEC or an EC type-examination certificate within the meaning of paragraph 5 of Annex III to that Directive, for a medical device incorporating that product or a product of that type.

Time for payment of fees under regulations 4 to 10

11. Unless regulation 44 applies, all sums payable by way of fees under regulations 4 to 10 must be paid within 14 days following written notice from the licensing authority requiring payment of those fees.