STATUTORY INSTRUMENTS

2013 No. 532

The Medicines (Products for Human Use) (Fees) Regulations 2013

PART 2

Capital Fees for Pre-Application Meetings

Fee for advice for other purposes

10.—(1) Unless paragraph (4) 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 £4,945.

(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 Union; or

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

(4) Paragraph (1) does not apply in the case of a meeting where the purpose of such a meeting is to provide only advice specified in regulations 4 to 9.

(5) In this regulation—

"Directive 93/42/EEC" means Council Directive 93/42/EEC concerning medical devices(**1**);

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

(**1**) OJ No L 169, 12.7.1993, p1. This Directive has been amended by Directive 98/79/EC of the European Parliament and of the Council (OJ No L 331, 7.12.1998, p1), Directive 2000/70/EC of the European Parliament and of the Council (OJ No L 313, 13.12.2000, p22), Directive 2001/104/EC of the European Parliament and of the Council (OJ No L 6, 10.1.2002, p50), Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ No L 284, 31.10.2003, p1) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No L 247, 21.9.2007, p21).

"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 EU instrument relating to EU marketing authorisations 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 interpreted in accordance with regulation 3 (sponsor of a clinical trial) of the Clinical Trials Regulations(**2**);

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 EU marketing authorisation, or making a variation to an EU marketing authorisation, for that product or a product of that type; or

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

(**2**) Regulation 3 has been amended by S.I. 2006/1928.