
STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

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

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 £4,810.

(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 authorization 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) OJNo. L 169, 12.7.1993, p.1. 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, p.1), Directive [2000/70/EC](#) of the European Parliament and of the Council (OJ No. L 313, 13.12.2000, p.22), Directive [2001/104/EC](#) of the European Parliament and of the Council (OJ No. L 6, 10.1.2002, p.50), Regulation (EC) No. [1882/2003](#) of the European Parliament and of the Council (OJ No. L 284, 31.10.2003, p.1) and Directive [2007/47/EC](#) of the European Parliament and of the Council (OJ No. L 247, 21.9.2007, p.21).

“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 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 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 authorization, or making a variation to an EU marketing authorization, 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](#).