STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

MEDICINES
FEES AND CHARGES

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

Made - - - -	*23rd February 2012*
Laid before Parliament	*29th February 2012*
Coming into force - -	*1st April 2012*

The Secretary of State for Health and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations in exercise of the powers conferred on them by section 1(1) and (2) of the Medicines Act 1971(**1**) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(**2**).

In so far as these Regulations are not made under section 1(1) and (2) of the Medicines Act 1971, the Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(**3**) and section 56(1) and (2) of the Finance Act 1973(**4**). The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products(**5**).

The Treasury has consented to the making of these Regulations as required by section 1(1) of the Medicines Act 1971 and section 56(1) of the Finance Act 1973.

In accordance with section 129(6) of the Medicines Act 1968(**6**), the Secretary of State for Health and the Minister for Health, Social Services and Public Safety have consulted with such organisations

(**1**) 1971 c.69; as amended by regulation 45(2) of S.I. 2008/2297 and section 21 of the Health and Medicines Act 1988 (c.49). By virtue of section 1(3) of the Medicines Act 1971 ("the 1971 Act"), expressions used in that section have the same meaning as in the Medicines Act 1968 (c.67) ("the 1968 Act"). *See* therefore section 1(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and the Schedule to, S.I. 1999/3142, by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794 and by regulation 44 of, and Schedule 8 to, S.I. 2006/2407. Section 1(1) of the 1968 Act contains a definition of the expression "the Ministers", which is relevant to the powers being exercised in the making of these Regulations. *See also* regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144) ("the 1994 Regulations"), by virtue of which the references in section 1(1) and (2)(b) of the 1971 Act to an application for a licence or for the variation or renewal of such a licence under Part 2 of the 1968 Act include reference to an application for a marketing authorization under the 1994 Regulations or for the variation or renewal of such an authorization.

(**2**) In the case of the Secretary of State, by virtue of article 2(1) of S.I. 1999/3142. In the case of the Minister for Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Department for which the Minister is responsible was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).

(**3**) 1972 c.68.

(**4**) 1973 c.51.

(**5**) S.I. 1972/1811.

(**6**) Section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

as appear to them to be representative of interests likely to be substantially affected by these Regulations.

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Medicines (Products for Human Use) (Fees) Regulations 2012 and come into force on 1st April 2012.

Interpretation

2. These Regulations shall be interpreted in accordance with Schedule 1.

PART 2

Capital Fees for Pre-Application Meetings

Interpretation of Part 2

3. In this Part—

"EU marketing authorization" means—

(a) a United Kingdom marketing authorization granted by the licensing authority under the Marketing Authorisation 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 European Union marketing authorization; and

"relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply.

Fee for scientific advice: application for, or variation to, EU marketing authorization

4. Unless regulation 5 applies, 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 EU marketing authorization or an application for the variation of an EU marketing authorization, is—

(a) £2,378, if the advice provided at that meeting consists of advice in connection with—

(i) quality development only; or

(ii) safety development only;

(b) £2,986, if the advice provided at that meeting consists only of advice in connection with clinical development;

(c) £3,309, if the advice provided at that meeting consists only of advice in connection with quality and safety development;

(d) £3,917, 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) £4,849, 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) 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) £2,986, if the advice relates to a product which, if reclassified, will be available on general sale; and

(b) £3,917, 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(**7**).

Fee for advertising advice

6. 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 that holder's undertaking on whether that advertising conforms to the requirements of Title VIII of the 2001 Directive, is £2,378.

Fee for pharmacovigilance advice

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

(a) £3,917, in a case where the time taken by the licensing authority to prepare for and attend the meeting is more than six hours;

(b) £3,308, in any other case.

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

Fee for advice on labelling or leaflets

8. 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 £2,378.

Fee for regulatory advice

9. 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 £2,986.

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

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(**8**);

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

"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(**9**);

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

(**8**) OJ No. 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).

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

(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.

Time for payment of fees under regulations 4 to 10

11. All sums payable by way of fees under regulations 4 to 10 must be paid within a period of 14 days, commencing on the date of the written notice issued by the licensing authority requiring payment of those fees.

PART 3

Capital Fees for Applications for Authorizations, Registrations, Licences, Certificates or Authorisations and for Associated Inspections

Fees for applications for authorizations, licences or certificates etc.

12.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the application fee for a marketing authorization (other than a European Union marketing authorization), a traditional herbal registration, a manufacturer's licence, a manufacturing authorisation, a wholesale dealer's licence or a clinical trial authorisation is—

(a) the fee prescribed for that application in Part 2 of Schedule 2; and

(b) in respect of an inspection of a site made in connection with that application, the fee payable in accordance with regulations 27 to 32.

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

Fee for applications for copy certificates of good manufacturing practice

13. The fee payable by an applicant for a certified copy of a certificate of good manufacturing practice issued pursuant to Article 111(5) of the 2001 Directive is £67.

Fees for applications for certificates and copy certificates by exporters of medicinal products

14.—(1) The fee payable by an applicant for a certificate issued under section 50 (export certificates) of the Act(**10**), is—

(a) £148, if the applicant requests the certificate to be issued within 24 hours of receipt of the application; and

(b) £67 in any other case.

(2) The fee in paragraph (1)(a) and (b) is for three identical signed certificates.

(3) The fee payable by the applicant for a certified copy of the certificate referred to in paragraph (1) is £33.

(**10**) Section 50 has been amended by S.I. 2004/1031.